Exhibit 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation

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This Document Relates to:

Roberts, et al., v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.
Case No: 1:20-cv-00946-RBK-JS

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REMOTE VIDEOTAPED DEPOSITION OF ANDREW THOMPSON, PhD

May 9, 2025
9:43 a.m. to 3:58 p.m.
REPORTED BY ANITA KORNBURGER
REGISTERED PROFESSIONAL REPORTER

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A P P E A R A N C E S

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I N D E X

E X H I B I T S

(Original exhibits attached to original transcript. Copies provided to all counsel.)

TRANSCRIPT OF PROCEEDINGS

THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Phillip Todd. I'm a videographer for Golkow, a Veritext division.

Today's date is May 9, 2025, and the time is 9:43 a.m. Eastern.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation related to the case Gaston Roberts, et al., vs Zhejiang Huahai Pharmaceutical Company, et al., in the United States District Court for the District of New Jersey, Camden Vicinage, MDL number 2875.

The deponent is Dr. Andrew Thompson.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely. Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Counsel will be noted on the stenographic record.

The court reporter is Anita Kornburger, and will now swear in the witness.

ANDREW THOMPSON, MD, called as a witness herein, having been first duly sworn on oath, was examined and testified as follows:

E X A M I N A T I O N

BY MR. SLATER:

Q. Morning, Dr. Thompson.

A. Good morning.

Q. My name's Adam Slater. You understand you're here for your deposition?

A. Do I understand what? I didn't catch that.

Q. Do you understand you're here for your deposition?

A. Yes.

Q. Have you ever had your deposition taken before?

A. I have.

Q. How many times?

A. Two times.

Q. What were those in connection with?

A. They were in connection with a patent case. There was two different generic companies that were trying to break a Merck patent four years before the expiration date, and since I was named on the patent, I was one of the people that the

Page 6

generics wanted to depose to see what I knew.
Q. When were those depositions taken, roughly?
A. 2014, about.
Q. Were you represented by counsel?
A. So Merck had counsel that they hired, and they were my counsel. So I was represented by Merck's counsel. I did not hire separate counsel.
Q. Who was that law firm?
A. I don't remember. I'd have to look it up. Shawn-something. I don't know.
Q. Do you have the transcripts from those depositions?
A. No, I do not.
Q. Did you ever read them?
A. No.
Q. They were never provided to you?
A. I didn't ask for them. I actually don't remember what the deposition transcripts were. I don't have them, and I don't remember asking for them.
Q. You understand you're under oath and must tell the truth in response to all of my questions today?
A. Yes.

Page 7

Q. If I ask a question that doesn't make sense to you for any reason, just tell me, okay?
A. Okay.
Q. The goal here is to get truthful and complete answers to every question. Do you understand that?
A. Yes.
Q. Therefore, if you can't understand a question or don't feel like you can answer it truthfully and completely, just tell me. Tell me what's unclear, we'll talk about it, and I'll try to ask a question that you feel you can answer truthfully and completely, okay?
A. Okay.
Q. During the course of the deposition your lawyer or other lawyers potentially may object. That's routine in a deposition. Lawyers object. They're preserving their rights to the future in terms of how this deposition testimony may be used. There's nothing improper about it.
Just please allow the objection to be made. And I would assume, in all or almost all cases, you'll be told to go ahead and answer the question, okay?
A. Okay.

Page 8

Q. And do you understand that even though this is an informal proceeding over Zoom, that this is of the same force and effect and the same gravity as if you were testifying right now sitting in a federal courtroom in the witness chair in front of a judge and a jury?
A. Yes.
Q. Did you prepare for this deposition?
A. Yes.
Q. What did you do to prepare?
A. I worked with counsel.
Q. Tell me what you did with counsel.
A. So we -- they told me the kind of questions I would get and just prepared me, like, emotionally to, you know, to deal with the -- the kind of back and forth that was going to take place in the deposition.
Q. For how long did you have that discussion over those subjects?
A. I'm going to guess now. Five hours.
Q. Did you prepare yourself substantively in terms of preparing by reviewing documents or testimony?
A. Yes, I reviewed the documents.
Q. Okay. For how long did you review

Page 9

documents to prepare for this deposition?
A. So from the very beginning when I started working on the case, or after I wrote my report?
Q. Yeah, I'm talking about -- rephrase. I'm asking about the preparation for the deposition itself. We'll talk about the time you spent writing the report separately.
A. So I probably spent 30 hours reading reports, rereading reports. You know, I had a question in my mind about what I actually said, so I would go back and look at the report, things like that.
Q. Let's mark as Exhibit 1 and put up the deposition notice, please. Actually, let's not put that up as Exhibit 1. Let's put up the defendant's response to the document request contained in the deposition notice. Actually, let me stop again.
MR. SLATER: You have the deposition notice, right, Chris?
MR. GEDDIS: Yep.
MR. SLATER: All right. As Exhibit 1, let's put up the deposition notice.
THE WITNESS: This is where I go to the room, that other room?
MS. ROSE: Not to the other room. If you

Page 10

go to the link for Golkow remote that you pulled up earlier and it says Dr. Andrew Thompson marked exhibits --

THE WITNESS: Oh, so that's -- so I got the more button. Which button do I press?

MR. SLATER: You can see it on the screen as well.

MS. ROSE: Here, Dr. Thompson, if you go to your -- either your Outlook or your Chrome, your --

THE WITNESS: Oh, okay. That's where it is. Oh, okay.

MS. ROSE: It should say Dr. Andrew Thompson marked exhibits. And you can just hit the refresh button, and then the document file should show up there.

THE WITNESS: All right.

BY MR. SLATER:

Q. Do you see it?

A. Should we work off this one that's being shared on the screen?

MS. ROSE: Yeah. You can open -- do you see Exhibit 1 now in that folder?

THE WITNESS: Veritext.

MR. SLATER: What I would suggest is

Page 11

we're going to put it on the screen. If for any reason I ask a question and you feel that you need to look at the whole document, we can either scroll to it or we can look at it if you need to look at it. I'm not going to stop you. I would just say wait to see if you need to depending on my questions.

MS. ROSE: I think the doctor would like to look at a document that you're introducing as an exhibit. So I just want to make sure he has access to the folder.

THE WITNESS: I do. It worked. I got it.

MS. ROSE: Okay. You can open Exhibit 1?

THE WITNESS: Yes.

MS. ROSE: Okay.

THE WITNESS: Yes.

BY MR. SLATER:

Q. Doctor, you see Exhibit 1 in front of you titled Notice to Take Videotaped Oral Deposition?

A. I do.

Q. Did you read that deposition notice?

A. Yes.

Q. Okay. Did you make an effort to provide the responsive information to the requests?

Page 12

A. Yes. So, I mean, it was pretty much boilerplate stuff like my CV, my invoice, and everything else. I didn't -- there was -- it didn't apply. So I have -- it was very easy for me to get the information that was being requested here.

Q. What did you provide to counsel in order to produce to us in response to this deposition notice?

A. So first thing, copies of all invoice. I sent -- I sent that to counsel. And then somewhere in here it's asking for my CV. Yeah, the CV. I sent that. And that was all I provided.

Q. Let's go now and mark as Exhibit 2 the response to the deposition notice, please.

A. Okay.

Q. On the screen we have Exhibit 2 titled Defendant's Response to Plaintiff's Document Requests Contained in Notice of Videotaped Oral Deposition of Dr. Andrew Thompson, PhD. Do you see that?

A. Yes, I do.

Q. Have you seen this document before?

A. No, I have not.

Q. Let's go to request number one. Request

Page 13

number one asked for all invoices for work performed in connection with any consultation or expert work performed for or on behalf of any defendant or their counsel with regard to any issues in this MDL, including but not limited to for the review of documents, review and consultation with regard to plaintiff experts, preparation of Dr. Thompson's report, and preparation for deposition or trial.

Do you see that?

A. Yes.

Q. We were provided one invoice dated May 6, 2025. Is that the only responsive invoice that you have?

A. Yes.

Q. Let's go to request three.

A. Okay.

Q. This requested copies of any notes, i.e., written or electronic reflecting consulting or litigation work on behalf of any defendant or their counsel with regard to any issues in this MDL that has not been documented in invoices. Do you have any such notes?

A. No.

Q. Let's go to request four, copies of any

notes or other documentation, including PowerPoints for any presentations, seminars or classes given by Dr. Thompson with regard to the chemical formation of nitrosamines under any circumstances, including those formed in ZHP's manufacturing process for valsartan API.

Do you have any such documents responsive to that request?

A. Okay, so I just want to read -- I get to read the response before I answer?

Q. Sure.

A. I mean, the answer is no, I don't have anything.

Q. You've never given such presentations, seminars or classes?

A. That's -- that's correct.

Q. Looking at request five, that asked for any notes or other documentation, including PowerPoints or any presentations, seminars or classes given by Dr. Thompson with regard to the technology and methods used for the identification of nitrosamines under any circumstances, including those formed in ZHP's manufacturing process for valsartan API.

Have you ever given such -- any such

presentations, seminars, or classes?

A. No, I have not.

Q. Go to request six: Copies of any documents or articles relied upon for the opinions set forth in the report served. Do you see that?

A. Yes.

Q. And do you have such documents or articles?

A. So everything I relied upon was mentioned in my report, and it was all from existing documentation that Najafi and Hecht that I referred to.

Q. If I want to know what you relied on I can read your report and see what you refer to?

A. So you're asking me what I relied upon?

Q. I'm asking if I want to know -- you just said everything you relied on is mentioned in your report. So I'm just restating that to make sure I understand.

If I want to know what documents or articles or materials you specifically relied on in forming your opinions, are they referenced and explicitly described or named in the report?

MS. ROSE: Object to the form. I believe Dr. Thompson talked about --

MR. SLATER: Please don't -- no, we're not going to start with speaking objections, Nina. It's an easy question. Come on. Please.

BY MR. SLATER:

Q. You can answer, Doctor.

A. Yeah, so everything I relied upon is in my report. But it says like I relied on the testimony of Najafi and references cited therein. So it's either in my report or it's by -- you know, it's referenced to in the Najafi report which has it in there. So that's what I mean when I say it's all referenced in my report.

Q. We'll come back to that.

A. Okay.

Q. Where are all the documents, articles and everything else that you reviewed as part of your preparation of your report? Where are they actually located?

A. They're on a -- they're on a -- on a folder on my computer.

MR. SLATER: Counsel, I'm going to ask that that folder be produced in complete form as soon as possible.

MS. ROSE: As stated in our objection, and as the witness just stated, he reviewed

documents that were provided by Drs. Hecht and Najafi which are equally available to plaintiffs.

MR. SLATER: I get that, but that's not the practice in this litigation. We saw what you wrote to us. We have a right to have everything he relied on to be produced to us so we can actually see what he actually relied on and reviewed as opposed to just telling us it's everything listed.

So we have a right to that. It's been produced for every expert in this litigation. It's what was supposed to be done. It's in one folder in his computer. I don't see any reason why, during a break, that can't be provided to us.

MS. ROSE: I disagree with that characterization of what's been provided by every expert. We can discuss on a break. I understand your request. No, I understand your request. I'm taking your request under consideration.

MR. SLATER: Okay. I'd like to have that resolved at the first break, please.

BY MR. SLATER:

Q. Looking at request seven, copies of any documents or articles reviewed in connection with the report served, whether listed in the report or attachments thereto.

Page 18

Would all such documents or articles be found in that folder that you told us about that's on your computer?
A. "Defendants state that they will provide additional responses as considered by the expert and" -- yeah, all the documents I relied upon would be in that folder, yeah.
Q. Look at request ten. We requested any documentation of any research grant the witness has been provided to study any angiotensin two receptor blockers, nitrosamines, or the identification of nitrosamines. Do any such research grants exist?
A. No.
Q. Have you ever done any study of angiotensin two receptor blockers?
A. So I worked on a -- I worked on one at Merck. It was a backup to losartan.
Q. What was it called?
A. It had an L number. It didn't have -- it didn't have a product name. It wasn't that far in development. And I don't remember the L number. And I don't have any documentation associated with it because when I left Merck, that was all property that belonged to Merck. I couldn't take any of that with me.

Page 19

Q. When you say it didn't get far in development, what does that mean?
A. I forgot how far it went. Maybe phase two. So it didn't make it to phase three, and it didn't make it to commercial. So only when compounds become commercial and they're approved by the FDA do they get a name like losartan. Before that they will have an L number, L with six digits. And if they get to a certain point, they'll have an MK number with four digits.
So the compound I worked on was the L number with six digits after it. And that's as far as the nomenclature got for that particular compound.
Q. When you say you worked on that, what was your specific involvement?
A. So I was involved in preparing the material.
Q. What does that mean?
A. So I would -- I would go into a laboratory with -- with reactors, put chemicals into the reactors, and do transformations from A to B to C to D, and come out at the end with a final drug candidate, the API.
Q. Would that be at the laboratory scale?

Page 20

A. Yeah. We did -- yeah. So we only -- I only worked on it up to the laboratory scale, several kilos, five kilos, and then the project was transferred to somebody else. From there they made larger quantities. But since it was somebody else in a different building, I kind of lost track of it.
Q. Were you responsible for the risk assessment of that drug, or was that someone else's responsibility?
A. That was somebody else's responsibility.
Q. From reviewing the materials and your background, it doesn't appear that you performed risk assessment as part of your work; am I correct?
A. Not formally, no.
Q. Have you ever done any research into nitrosamines?
A. No, I have not.
Q. Have you ever done any research into the identification of nitrosamines?
A. After 2018, when this issue became a big issue in the pharmaceutical industry, I had to learn about nitrosamines -- this is all on paper, right, not in a lab -- but I had to learn about them, how they form, and methods for their

Page 21

detection. I had to become versed in that so I could talk to my customers about it.
Q. You were not familiar with those subjects before you learned about the nitrosamines found in the valsartan drugs in 2018?
A. That's correct.
Q. In your work do you or did you operate gas chromatography?
A. Yes.
Q. In your work do you or did you operate gas chromatography mass spectrometry machines?
A. Yeah, a little bit. But most -- most of that work was done by people that reported to me. I had gotten to the point where I wasn't in the lab anymore, and I was a manager. So I wasn't doing hands-on chemistry. I was watching over people doing it.
Q. When did that happen that you became a manager?
A. You know, it didn't happen all at once, not like overnight. Gradually I shifted out of the lab. So I probably shifted out by 2025. I wasn't really doing -- I'm sorry, 2005 I wasn't really doing much in the lab after that.
Q. Do you know how to operate a GCMS

Page 22

machine?
A. No. I would have to read instructions on how to do it at this point.
Q. When's the first time in your life you ever heard of NDMA?
A. NDMA?
Q. Yep.
A. So I can't recall exactly, but I would say it was about -- it was from the valsartan recall that I first heard about it. I did not -- I don't think I ever heard of that compound's name prior to the valsartan recall.
Q. When did you learn of the existence of nitrosamines?
A. After the valsartan recall.
Q. Look at request twelve, copies of any documents, including protocols or information about the chemical formation of nitrosamines under any circumstances available to the witness from any laboratory or academic institution where he has worked, had an appointment, or had access which set forth information related to the chemical formation of nitrosamines under any circumstances and the technology and methods used to identify nitrosamines. Do you have any such documents?

Page 23

A. I do not.
Q. Request 14, please. Any communications from the witness to any person or entity with regard to nitrosamine impurities in any angiotensin two receptor blocker or other drug outside of communications to counsel who retained the witness. Do any such communications exist?
A. No, they do not.
Q. So your only communications with anybody in the world about nitrosamine impurities as described in that request would be in the context of your communications with counsel; correct?
MS. ROSE: Object to the form. Misstates the witness.
BY MR. SLATER:
Q. Is that true?
A. Yeah. So any nitrosamine impurities in an A2 receptor blocker, yeah, so the only people I discussed that with is counsel.
Q. This also says any other drug. That would be true of any drug; correct?
A. Yeah, any -- so any -- I mean, we talked about -- after 2018 we talked about these things, but there was no written communications. I wouldn't have access to those e-mails now. And

Page 24

there's really -- there's really nothing other than what analytical technique we would use to detect them.
Q. You said after 2018 with regard to other drugs you talked about these things. Who with?
A. So I had an analytical group. So there was a person in charge of the analytical group who reported to me. And then she had about 25 people under her. And then I had a QA group also, quality assurance. I don't think I talked with Mike about it.
But with Leigh we talked about, you know, what we were going to do to be able to assay for nitrosamines, what was -- what was -- what techniques we were going to do, how we were going to do this. You know, what was I going to tell customers we had in place for it.
Q. That was not something you had considered before that time; correct?
A. I didn't -- no, I never considered any analytical technique to detect nitrosamines prior to 2018.
Q. Did you ever consider the potential presence of nitrosamines in any drug before 2018 when you learned of the valsartan issue?

Page 25

A. No.
Q. Okay. We can put that document down and we can go to Exhibit 3, which is the invoice.
A. Okay.
Q. We marked as Exhibit 3 a document that says at the top confidential. It's dated May 6, 2025. It says, "The following table shows the days and hours utilized for the valsartan project in March and April 2025." Do you see that?
A. Yes, I do.
Q. Is this an accurate listing of what you did on each of those days for those amounts of time?
A. Yes, it is.
Q. Did you have a chance to review this and make sure it was absolutely correct before today?
A. Well, I put this thing together, so I didn't have to really review it. But I did have a chance. But I'm the one who put this together, so I didn't have to review it.
Q. How were you first contacted to become involved in this litigation?
A. So I received a phone call from -- I assume he's an attorney -- Paul, asking me, you know, if I wanted to consult on a certain issue,

and I think feeling out my capabilities to decide if I was an adequate fit for the law firm and if I was interested.

So I received that call probably before March 22nd, or maybe that was the first call we set up a Zoom call. I can't remember exactly how it started. But I received a call from Paul. And he --

Q. Okay. And that would have taken on or about March 22, 2025?

A. Yes.

Q. Do you know Paul's last name?

A. Kolter. I don't remember exactly. Kolter.

Q. Do you know what law firm he works at?

A. Kirkland.

Q. Have you ever been retained to consult or act as an expert witness in any litigation before this one?

A. No. I mean, just -- just the Merck -- just that Merck patent situation. But...

Q. That one you had personal involvement with 'cause you were on the patent; right?

A. Right.

Q. So other than this litigation where

you've been asked to be an expert witness, have you ever consulted or been an expert in any other litigation where you didn't have personal involvement?

A. No.

Q. Do you know how Paul found you, why he identified you as a potential witness in this case?

A. Yes, I do.

Q. How did that happen?

A. This is from what Paul told me, but he had called a friend of mine who's a professor at Vanderbilt -- and I don't know what they discussed -- but that friend of mine recommended me to -- recommended Paul call me.

Q. Who's that professor at Vanderbilt? What's his name?

A. Gary Sarnakowski (phonetic.)

Q. How do you know him?

A. I know him from graduate school.

Q. Are you friends?

A. Yes, we are.

Q. Did you ever work with him?

A. No. I mean, he worked in the same group that I was in at Penn, but we never -- I never worked for him, no, or with him on the same

project.

Q. Do you know anybody that, to your knowledge, has been or is affiliated or works with ZHP?

A. No.

Q. How about their United States entities, Solco, Prinston, or Huahai US?

A. No, I do not.

Q. Had you ever heard of ZHP before you were contacted on this case?

A. No.

Q. Have you spoken to anybody at ZHP, Solco, Prinston, or Huahai US?

A. No.

Q. As part of the work that you did in this case, did you request any documents from counsel, or did you just review what was provided to you?

A. I reviewed what was provided.

Q. Did you do any independent research?

A. No, there was -- the documents that were included in the witness testimony were adequate for me to make my decision to have an opinion.

MR. SLATER: Move to strike after no.

MS. ROSE: Object. Adam, we've been getting strong, strong objections that moving to

strike is --

MR. SLATER: Oh, you're right, Nina. You know what? I forgot. Thank you for calling me. I was -- I've been doing state court litigation again and -- where you do move to strike. So I agree. I'll withdraw the motion to strike because our ability to move to strike testimony is preserved without having to say it. Sorry, I forgot. Thank you for reminding me.

MS. ROSE: No problem.

MR. SLATER: It's hard to teach an old dog new tricks.

THE WITNESS: Tell me about it.

BY MR. SLATER:

Q. Did you do any independent literature search as part of your work in this case?

A. No.

Q. From reading your report -- which we'll come back to -- I'll rephrase.

From reading your report, it appears that your expertise is in the field of organic chemistry; is that correct?

A. Organic synthesis, yes.

Q. Let me rephrase it then. In terms of what you're holding yourself out as an expert in

Page 30

this case on, is it organic synthesis?
A. Yes.
Q. What does organic synthesis mean?
A. It's preparing -- synthesizing new molecules from existing building blocks. So it's the actual steps you take to make a chemical bond to change one molecule into another one.
Q. If I understand that correctly, you're talking about the actual development in the laboratory of the drug substance?
A. It's the synthesis -- it's the development of the synthesis of the drug substance.
Q. When you say the development of the synthesis, just tell me more specifically what that means. When you refer to the synthesis, is that the actual method to manufacture that drug product?
A. Yes, drug substance.
Q. Is that the intent, that that drug substance would ultimately be developed into an API?
A. Yeah, the drug -- the synthesis that we're working on, the last step of the synthesis is the API, prepares the API.
Q. And that's all at the lab scale; correct?
A. At kilo lab scale.

Page 31

Q. Is kilo lab scale otherwise known as pilot scale?
A. It's just before. So pilot scale I consider to be 50 kilos, hundred kilos. And kilo lab is five to ten kilos. And they supply different phases of development.
Q. So your development work has been at the laboratory level up to five to ten kilos of product?
A. Yeah. We prepare product for phase one clinical trials. Substance, I'm sorry.
Q. If I understand correctly, your development work would be at the lab scale up to five to ten kilograms. And then if development process were to continue after that, it would then go to pilot scale, and that would be another -- those would be other people that would conduct the pilot scale?
A. Yes, as is typical in the industry. That's the way it's done.
Q. When I look at the description in your invoice of what you did, it refers to Zoom calls, document review, and report preparation. In terms of the document review, would you be able to tell me what documents you're reviewing at any

Page 32

particular time during this process, or is it just more generic that you know you were reviewing documents?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Do you get what I'm saying? I'm asking if you were able to say on this day it says document review, but I know on that day I was reviewing these documents.
MS. ROSE: Object to form.
THE WITNESS: No, I can't -- I can't say that.
BY MR. SLATER:
Q. When it refers to report preparation, what does that mean?
A. The witness report that was -- was provided. So there's reading documents, forming an opinion, and then actually writing the report.
Q. Just to come back to one thing we were talking about a moment ago. You said that your expertise that you bring to this case is in the field of organic synthesis; correct?
A. Yes.
MS. ROSE: Object to the form.
THE WITNESS: Sorry.

Page 33

BY MR. SLATER:
Q. You're not holding yourself out as a regulatory expert in this case; correct?
A. Correct.
Q. You're not holding yourself out as an expert in current good manufacturing practices and providing opinions on that; correct?
A. That's correct.
Q. You're not holding yourself out as an expert in risk assessment process for drugs; correct?
A. That's correct.
Q. You're not holding yourself out as an expert with regard to the content of the organic chemistry literature; correct?
MS. ROSE: Object to the form.
THE WITNESS: I'm not holding myself out as an expert on the content of organic chemistry literature?
BY MR. SLATER:
Q. Yes, in terms of what was in the literature, and when.
MS. ROSE: Object to the form.
THE WITNESS: So if -- if I read a paper on organic chemistry, so this is, I'm an expert?

Page 34

If you're asking me do I have encyclopedic knowledge of every publication on organic chemistry since the time they started publishing, I don't know that.
BY MR. SLATER:
Q. You did not do any independent study or analysis of what subjects were in the literature at particular times? You didn't independently evaluate that question; right?
MS. ROSE: Object to the form.
THE WITNESS: No, I did not.
BY MR. SLATER:
Q. In looking at your invoice again, on April 10, 2025 it says document review and report preparation. Do you see that entry?
A. Yes.
Q. I don't see any other entry referring to report preparation. So can I -- rephrase it. Let me start over. I'm sorry. I lost my train of thought.
When I look at your invoice, on April 10, 2025 there's a reference to document review and report preparation. There are no subsequent references to report preparation. Does that mean that you had finished preparing your

Page 35

report as of April 10th, and then you just continued to review documents and had Zoom calls after that time?
A. Yes.
Q. Why did you continue to review documents and have Zoom calls after your report was done? What was the purpose of that ongoing review and those calls?
A. So, you know, I didn't just stop, write the report, put it down, and forget the whole case, right? There were questions I had, thought processes I had that I wanted to go back and clarify further by reading documents in more detail so I could get a clearer picture in my mind of everything that happened, 'cause, you know, there's a lot of documents, and I wanted to read things, especially the DIR, what are they called, deviation investigation report. I wanted to read that in more detail than I had.
So I would read the things -- like Najafi and Hecht would reference certain -- certain DIR -- certain places in the DIR. I would read those. But then I went back and read it more thoroughly from start to finish after I wrote the report to get myself up to speed fully.

Page 36

Q. But the report had been completed by April 10th; right?
A. Yes.
Q. Did you read any depositions as part of your review of materials?
A. Yes, I did.
Q. Which depositions did you read?
A. I read the deposition of Hecht. I read the deposition of Najafi. I read the deposition of Min Li. I read the deposition of somebody else who I can't remember his name from -- from ZHP. And those are the four depositions I can remember reading.
Q. Do you recall the role of the person whose name you can't recall at present?
A. Yeah, he was like the VP of the company. He was high level.
Q. Jun Du?
A. I think so.
Q. You mentioned him in your report, so I'm trying to help you out.
MS. ROSE: Objection, form.
MR. SLATER: Object to my help. Actually, that's a good objection.
BY MR. SLATER:

Page 37

Q. Okay. You can think about it, but as you sit here now, do you feel that probably that fourth person was Jun Du?
A. I'd have to look at the name on the deposition.
Q. Okay. I'll make a note. I may come back and ask you that maybe after a break. I don't want you to do anything now.
A. Okay.
Q. Did you read the entire deposition transcripts for every one of those witnesses, or parts of them?
A. I think I read the entire deposition transcript. I found it interesting.
Q. Do you know how long it took you to read the deposition transcripts of Dr. Hecht?
A. Yeah, I was clocking myself at, it was less than a page a minute. It was a little faster than a page a minute, but it wasn't two pages a minute. Something like that, one-and-a-half pages a minute, something like that, it was taking me to read it.
Q. You actually have a -- you kept track of the time to read per page?
A. Yeah. I would look at -- look -- before

Page 38

I start, I'd look at the clock. Yeah, 25 pages later I'd look at the clock again. How fast am I going, you know?
Q. Did you take notes while you were reading these deposition transcripts?
A. No.
Q. You just read them?
A. I read them, yeah.
Q. Did you highlight them or put notes on them?
A. No. If I'm taking notes, I'm not at the meeting.
Q. Did you read the entire deposition transcript of Dr. Najafi?
A. I believe I did. But there was two of them. Yeah, there was two of them. I believe I read both of them, one day after the other.
Q. Did you read all the deposition transcripts of Min Li?
A. I did. There was two of those too.
Q. You saw two transcripts of Min Li?
A. I saw two different days. I believe there were two different days.
Q. Did you read all the testimony of Jun Du, all of his transcripts?

Page 39

A. For some reason I thought I only had half of that. So I'm -- I'd have to go back and see what things I read for Jun Du.
Q. Did you ever hear of Dr. Hecht before you got involved in this case?
A. No. And I had him confused with somebody else. Sidney Hecht. There's a Sidney Hecht at the University of Virginia. That's who I thought it was. But his -- what's his first name? His name is --
Q. Stephen Hecht.
A. Stephen Hecht, yeah. No, he's somebody else. So no, I had never heard of him before this. Sidney, Stephen, you got me confused, you know.
Q. There's a series of Zoom calls interspersed. Who are those Zoom calls with? You had told us about the first one with Paul. How about on a going-forward basis, who else did you speak to on Zoom calls?
A. So there was Nina -- these are the people I can remember, which I think is complete: Nina, Jessica, Archer and Louis.
Q. Is there additional time you have spent after April 30th, which is the last entry on this invoice? Obviously you're here for the deposition

Page 40

today. But between April 30th and today have you spent additional time?
A. Yes.
Q. What have you done between April 30th and the present?
A. I continued with document review and preparation for the deposition.
Q. Let's go to exhibit -- I guess we're up to four. Let's go to Exhibit 4, which will be the expert report.
MS. ROSE: Doctor, are you able to see Exhibit 4 on --
THE WITNESS: Yeah. I'm not -- I'm still trying to bring it up. I can only get as far as Exhibit 3.
MR. SLATER: No problem. It's probably just being loaded.
THE WITNESS: No, it's still only going as far as Exhibit 3. There we go. Okay, I can see it.
BY MR. SLATER:
Q. Doctor, do you see in front of you Exhibit 4, which is your expert report?
A. I do.
Q. And it looks like the body of the report

Page 41

itself is ten pages -- ten pages. I see it was signed by you electronically on April 10, 2025; is that correct?
A. I'm just scrolling down to page 10. But that sounds like -- yeah, that's -- that's it. That looks like it, yes.
Q. You state right above the signature, "I hold these opinions to a reasonable degree of scientific certainty." Do you see that?
A. Yes.
Q. What does that mean?
A. I would say that I used the same scientific rigor to prepare this report that I would use to conduct my research.
Q. When you refer to conduct your research, what research are you referring to?
A. So to conduct the synthetic -- the chemistry that we did -- or the research that we did at J-STAR, the research that we did at Merck, there was a level of scientific rigor that I applied in that research. And I applied that same level of rigor to preparing this report.
Q. And what did that research involve at those times, figuring out how these different substances you were working with could create the

Page 42

desired drug substance?
A. Working on the synthesis, solving problems, yes.
Q. So if I understand correctly, when you were actively working in the lab, you were -- you were part of the team that was actually figuring out how do we make this substance? That might be simple, but is that right?
A. Yes, what steps do we use, what chemistry do we use.
Q. Going back to your work at Merck. Is that what you did at Merck?
A. Yes.
Q. Then it looks like you started a company called J-STAR; correct?
A. J-STAR Research, yes.
Q. And what is J-STAR Research?
A. What do they do?
Q. Yep.
A. Okay. So if I talk too long about this --
Q. Give me -- let me cut you off. Tell me at a high level what J-STAR does, and then we'll get into a little more as we talk today.
A. Okay. So J-STAR -- so at Merck I worked

Page 43

in the department of process research. That was one department at Merck. There was a medicinal chemistry department. There was the department of the process research. So J-STAR was the department of process research that a company could outsource to to get that kind of work done.
If you didn't have your own department and didn't want to spend the money to build it and hire the people, you could rent it from us. And when you were done, you handed back the keys and stopped paying for it. That was the product that I was selling.
Q. So J-STAR was a contract process research laboratory?
A. Contract research laboratory, CRO.
Q. When J-STAR would be contracted for a specific project, would the manufacturer -- what would the manufacturer provide to J-STAR in order to get J-STAR going? Would it just be a general idea? Would it be actual synthesis analysis? Would it be actual development ideas? What would they give you to get started?
MS. ROSE: Object to form.
THE WITNESS: All of the above. Oh, sorry.

Page 44

MS. ROSE: If you could wait, Doctor, for a second. I'm trying to get in there quick.
THE WITNESS: All right.
MS. ROSE: If you could give me a second to object, like Mr. Slater said at the beginning of the deposition, that would be very helpful. Thank you.
THE WITNESS: Okay. So it wasn't the manufacturer that provided. It was -- it was the owner of the intellectual property. And they would sometimes provide us with a synthesis, sometimes provide us with a target and no synthesis, or partially a synthesis. Usually they had some synthesis problem they needed solved that we solved for them.
BY MR. SLATER:
Q. When you say the owner of the intellectual property as opposed to the manufacturer, can you explain to me the distinction, please?
A. Yes. So the owner -- the manufacturer is just another contract lab like J-STAR, okay? I didn't own the intellectual property. The manufacturer doesn't own the intellectual property. There's an entity, that's the biotech, they -- and

Page 45

they're funded by venture capital. They own the intellectual property. And they contract out all the aspects of the development. So I consider the manufacturer another contract -- contractor in the supply chain.
Q. Would that apply to Merck? For example, would you see Merck as a manufacturer in that context as you define those terms?
MS. ROSE: Object to the form.
THE WITNESS: So Merck is a different beast. Merck would never be a customer -- not really be a customer of mine. Merck had everything internally. They were the owner of the intellectual property. They had the process research group, and they had the manufacturing assets and drug product and marketing. They had everything, soup to nuts. They didn't need to contract out to anybody. They had it all. All the big pharmas are like that.
BY MR. SLATER:
Q. Okay. And that's helpful, 'cause I wanted to understand who your client base was at J-STAR. And I understood that maybe you were working with companies like Merck or Johnson & Johnson or other companies that actually, as you

Page 46

said, have -- have all of these different facets internally. But those would not have been your customers at J-STAR?

A. So Merck sent us a little bit of work. We had some work with large companies that had all those things. But the bulk of our work was with smaller companies, merging pharma companies.

Q. When you say that you would be provided the -- I'm going to call it the assignment or contract with the owner of the intellectual property -- what would they be giving to you to get you started? How would that typically happen?

A. They would give me a tech package, and the tech package would outline usually the target, whatever synthesis they had in place at that point, and all the requirements they wanted me to take care of. And they wanted me to quote on what it would cost to do all that, and a timeline.

Q. When you refer to the target, what does that mean?

A. The target is the API.

Q. In terms of what it was intended to be able to do? Let me ask it differently.

When you say the target is the API, just tell me exactly what it is that that means to

Page 47

you. I don't want to inartfully describe it.

A. So that's the chemical structure of the API. I would get -- I would get provided the chemical structure. And the chemical structure of the intermediates and the steps they used to convert the intermediates to the API. Chemical structure is all I got.

Q. And you would then take that chemical structure and attempt to synthesize it into an actual API that could be produced in the lab?

A. So I would take their synthesis and eval -- we would evaluate it to see if it was practical for scale up to kilogram scale. And if it wasn't, we would suggest to the customer you need to fix this step, you need to look at this here, you need to do this, you need to do that.

But by and large, yes, I would take the chemical structures, I would buy the starting materials from a chemical company or raw materials supplier, and I would buy the reagents to do the chemistry, and we would do the conversions. But there was -- there was a lot of research that went into it before we started making material.

Q. When you say there was a lot of research, would that be the research into developing a

Page 48

process whereby you could actually manufacture the API?

A. Yes.

Q. So in other words, the how to?

A. The how to, yeah.

Q. In doing some research, it looked like your company was purchased or acquired by another company called Porton, P-O-R-T-O-N. Is that correct?

A. Yes.

Q. And from my reading, it looks like that took place in 2017?

A. Yes.

Q. What is Porton?

A. So Porton's a bigger fish. They're a manufacturer. And so they were -- they're based in China, central China, next to outer Mongolia. They wanted to have a presence in the United States. To get that presence, they bought us.

Q. Did your company's name change at that point, or were you just then a wholly-owned subsidiary of Porton?

A. We were a wholly-owned subsidiary of Porton.

Q. Did Porton have control over your

Page 49

operations as the owner?

A. Yes, they did.

Q. Did your company develop substances for manufacture in China?

A. Yes, we did.

Q. What substances were those?

A. So that's kind of proprietary information, but -- and it didn't happen all the time, but there were certain cases where somebody wanted a metric ton of an intermediate and the synthesis wasn't even capable of making a gram. So we'd work out the process in the United States, and then we'd send that process to the chemists in China, and they would make the metric ton out of it. So that was the idea behind the purchase.

So we would get the business on the small scale, work it out or send it directly to China. That was the idea.

Q. So in those cases you would figure out at the lab scale how this could be manufactured and think it through and then send them to -- that process and they could then attempt to manufacture at a larger scale in China when that happened?

A. Yes. So when that happened, they didn't need us to make five kilos, 'cause they can

Page 50

make -- so we would give them the recipe. Here's the recipe, you know, A, B, C, D instructions. Here it is. You can take it from -- and we would give it to a technical group in China, and they would take over from there.

Q. Did you travel to China at any time as part of this work?

A. I did.

Q. How often?

A. Two or three times a year.

Q. Why was that?

A. So they would have, like, corporate board meetings, and they just liked to be face to face, so -- and they had operations all over the world. It wasn't just New Jersey. They had operations in Switzerland. They had operations in Belgium. And -- and all of those people would get together for a board meeting. So I'd get to meet all those people. We'd have dinner together.

MR. SLATER: I'm happy to keep going. I know, Nina, sometimes you like to take breaks. It's up to you. This would be a good breaking point. But if you want to keep going, I can go without stopping.

MS. ROSE: You hit one hour on the nail,

Page 51

Adam. So, yeah, it's a perfect time for a break.

THE WITNESS: Okay, great. Be back in two minutes.

MR. SLATER: Let's give it five. See you soon.

THE VIDEOGRAPHER: We're off the record -- would you like to go off the record?

THE WITNESS: Yeah, five minutes, right? I heard you.

MS. ROSE: Yeah, just five. Mute --

THE VIDEOGRAPHER: We're off the record --

MS. ROSE: We're off the record.

THE VIDEOGRAPHER: No. We're off the record at 10:44 a.m. Thank you.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 11:05 a.m.

BY MR. SLATER:

Q. Okay. Doctor, I'm looking at your report now which we marked as Exhibit 4. Do you have that in front of you?

A. I'm going to get -- yes, I do.

Q. Okay. I'm looking right at the first paragraph.

Page 52

A. Hold on. I gotta scroll all the way up to the top, 'cause I was at the signature page. The first paragraph, "I have been asked." That one?

Q. Exactly.

A. Okay.

Q. Looking at the first paragraph on page 1 you wrote, "I've been asked to review and respond to certain statements made in expert reports submitted by Drs. Ramin Najafi and Stephen Hecht in connection with this litigation." And I just want to stop there.

When you refer to reviewing and responding, did you understand that your role here was to look at what they said and then give your reaction to what they were saying?

A. Yeah, my role was to give my opinion on their opinions.

Q. And that's what you say in the next sentence, specifically, "I have been asked to evaluate opinions by Drs. Najafi and Hecht regarding the state of knowledge in the field of chemistry and, in particular, by chemists involved in the development and manufacture of drug substances regarding the potential for formation of

Page 53

nitrosamines in valsartan drug substance manufactured by ZHP prior to the discovery of trace amounts of NDMA in the drug substance in 2018."

And that's -- that's -- is that a good explanation of what your role was here and what you brought your expertise in on?

A. Yes.

Q. And again, you didn't do anything independent in terms of research. As you told me before, you looked at their depositions, you looked at their reports, you looked at the documents you were given, and reacted to that information; correct?

A. Yes.

Q. And when you provided your opinions based on your evaluation, it's my understanding you were basing that on your experience based on your work that you've done over the years in the chemistry field; correct?

A. Yes.

Q. You were not applying, that I saw from the report, any specific standard or outside criteria to measure what was known or should have been known. You based it on what you know based on your work and your own experience; correct?

Page 54

MS. ROSE: Objection, form.
BY MR. SLATER:
Q. Let me ask it differently. In terms of the standard that you applied in evaluating what Drs. Najafi and Hecht said, am I correct that you measured what they said against what you're familiar with from your work and what you know from your practice of organic chemistry or synthesis as you described it? Do I understand that correctly?
A. Yes. I mean, it's in particular to impurities and how impurities are identified. That's kind of the focus of my opinion, how you identify -- how you first notify and how you identify impurities. That's what I'm referring to, yes.
Q. And in terms of how that is done and what needs to be looked for, you base that on your own experience working in a lab; is that correct?
A. I base it on my -- on my experience with all the APIs I've ever developed over 35 years. Somebody's trying to come in. That might not be good, unless that's just the mailman. Hold on. Just give me a sec.
MS. ROSE: Should we go off the record?
MR. SLATER: Sure.

Page 55

THE WITNESS: No, I think we're okay.
MR. SLATER: No, no, we're back.
THE WITNESS: My concern is that one of my three-year-old grandkids is going to come tearing through here and -- you know, and interrupting. No, it's okay. That's not happening.
BY MR. SLATER:
Q. If they come in, we gotta put them under oath.
A. I know. That's why I don't want them coming in.
Q. Let's go to the second page of your report, please.
A. Okay. Okay, so you're going over there. Okay. Second page.
Q. You have a heading that says Basis for Opinions. And that's listing an overview of what you reviewed; correct?
A. Yes.
Q. Now in reviewing this you refer to, for example, the deposition or the depositions of Dr. Hecht and exhibits. Do you see those bullet points at the bottom of the page?
A. Yes.

Page 56

Q. Did you read every single exhibit from every single deposition that's listed here?
A. No.
Q. Do you know which exhibits you read and which you didn't read?
A. I can't recall off the top of my head.
Q. Does this report contain all of the opinions that you have formed in this case?
A. Yes.
Q. And you understand that's the purpose of the report being written, is to give notice to us, the plaintiffs, as to what your opinions are so we can understand what opinions you may give at trial. You understood that; right?
A. Yes.
Q. In the course of the report you talked about certain facts. You cited to certain testimony, certain parts of the expert reports, certain documents. Are those the specific items that you found to be most important to you in forming your opinion here?
A. Yeah, if I'm citing something, it's -- it's cherry-picked most important documents to me, yes.
Q. Let's go to page 3 if we could.

Page 57

A. Okay.
Q. You state in section three, Opinions, "Over the course of my 38 years of work in the pharmaceutical and drug development industry, I've been involved in the development of more than 250 APIs." I'm going to stop there.
Were these APIs new drugs or at least intended to be new drugs, or were they generics in the sense of trying to be the generic equivalents of something else that was already a brand drug?
A. I would say greater than 99 percent of them were new branded pharmaceutical -- were going to be new branded pharmaceuticals, new drugs.
Q. You state in the second sentence of that section, "In developing every one of the API substances I worked with over the course of my career, I and my team made an effort to anticipate impurities that may form in the production of the drug substance." Do you see where I'm reading?
A. Yes.
Q. When you say an effort to anticipate impurities that may form in the production of drug substance, what does that mean?
A. So I would look at the chemical structure, I'd look at the reaction we were doing,

Page 58

and the conditions, and if I could see a possible reaction pathway that I didn't want to happen that would generate an impurity, I would try to anticipate those. I would try -- I would try to figure out what could go wrong in every step. Me and my team would do that.
Q. Did you do so based on your experience and knowledge?
A. Yes.
Q. Did you do independent literature or other scientific research as part of that?
A. Sometimes.
Q. You indicate, "For example, after 2015 ICH M7 -- addressing genotoxic impurities -- was adopted by the FDA, the potential formation of genotoxic impurities was a consideration with respect to every API that we developed"; correct?
A. Correct.
Q. What's ICH M7?
A. So I'm not the regulatory expert; I think we established that in the beginning. But my understanding of ICH M7 is that that's the guidance that came out specifically relating to genotoxic impurity presence in API.
Q. Did you ever read the ICH M7?

Page 59

A. I did.
Q. Did you ever read the prior versions before 2015?
A. The guide -- the draft guidance?
Q. The draft of ICH M7 going back to 2013, did you read that?
A. I had a hard time finding that. I don't know if I ever found it or could read it. I don't remember.
Q. Do you understand what a genotoxic impurity is?
A. I have my understanding.
Q. What's your understanding?
A. It's typically an alkylating agent that reacts with DNA and causes a disruption in the D -- in the DNA structure, change of base.
Q. You referred to the potential formation of genotoxic impurities; correct?
A. I'm trying to see where it says --
Q. That same sentence I asked you about.
A. Yeah.
Q. And you would agree with me that's -- that's what the developer of a drug substance would need to be aware of potential formation; right?

Page 60

A. Yes.
Q. You don't have to know that it's definitely going to form before you start to be concerned; right?
MS. ROSE: Object to the form.
THE WITNESS: It's also not a hundred percent going to cover every situation. It's only the ones you can think of.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. My question is this --
MS. ROSE: Adam, I'm sorry --
MR. SLATER: I did it again. I'm sorry. I apologize. I withdraw that.
BY MR. SLATER:
Q. I wish someone was here to hit me with a ruler, you know, on the hand.
A. We are.
Q. When you refer to the potential formation, that's what you need to be concerned about. It's not that you have to know something is going to form before you have a concern; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, you want to -- if you know it's in there, if you put it in there, for

Page 61

example, put it in there, you know it's going to be there, and things you can think of that could potentially form. Again, the emphasis in that sentence is things you can think of. It doesn't cover things you can't think of or you haven't -- you didn't think of.
BY MR. SLATER:
Q. Do you know what standards applied to the people at ZHP who were the process chemists in terms of what the standard was for them in terms of what they were supposed to do in order to evaluate potential formation of genotoxic impurities? Do you know what standards applied to them?
MS. ROSE: Object. Outside the scope of his expertise.
THE WITNESS: And the answer is no, I do not.
BY MR. SLATER:
Q. So if I'm understanding, you did not apply any specific, for example, published standard or standards in evaluating what the people at ZHP could or should have known about with regard to potential impurities, specifically genotoxic impurities; correct?
MS. ROSE: Object to the form.

Page 62

THE WITNESS: No. I didn't know what standards they were applying. I couldn't possibly have done that.
BY MR. SLATER:
Q. And you didn't apply any specific standard in evaluating this material; correct?
MS. ROSE: Object to the form.
THE WITNESS: In evaluating the valsartan material?
BY MR. SLATER:
Q. The material in this case, you didn't apply a specific standard or standards in reaching your opinions; correct?
MS. ROSE: Object to the form.
THE WITNESS: I didn't -- I didn't apply any known risk analysis, formal risk analysis, to it.
BY MR. SLATER:
Q. For example, you didn't go back, for example, to any of the FDA or ICH guidances with regard to genotoxic impurities, look for what they said is supposed to be done in terms of assessing the risk for genotoxic impurities, and apply those standards? That's not something you did; correct?
MS. ROSE: Object, outside the scope.

Page 63

THE WITNESS: I read the guidance to see what the -- the levels should be and how you would determine them. In all cases, things -- the way I read the guidance, things you know about, or things you can anticipate, you have to control. But the way I read it, if you didn't anticipate it, you couldn't possibly control it. That's the way I read the guidance.
BY MR. SLATER:
Q. Is that the M7 you're talking about?
A. Yes.
Q. In evaluating what ZHP knew or should have known, did you apply their internal standard operating procedures or internal protocols?
A. Did I apply ZHP's internal standard operating procedures?
Q. Correct.
A. No. I just gotta take a minute. Can I come back in a minute?
MR. SLATER: Can we go off?
THE VIDEOGRAPHER: We're off the record at 11:22 a.m.
(Break taken.)
THE VIDEOGRAPHER: We're back on the record at 11:25 a.m.

Page 64

BY MR. SLATER:
Q. Doctor, you said that if you don't anticipate it, you can't control it a moment ago. Do you remember that?
A. If you don't anticipate it, you can't put in protocols to control it. It's a little more than that, actually. If you don't anticipate it, and you don't see it on a chromatogram, you don't see any evidence of it, so you didn't think of it, and you don't see any evidence in your data that it's there, yeah, you're going to miss that one.
Q. And when you say if you don't anticipate it, you're not saying that in all cases the failure to anticipate that there's a potential formation of a genotoxic impurity is excusable? You're not saying that; right?
A. In all cases it's excusable if you don't anticipate it. No, I'm not saying that.
Q. Because the -- based on your experience in your lab, you would give some thought to it and you would hope that you anticipate potential impurities; right?
MS. ROSE: Object to the form.
THE WITNESS: Yes, so that's -- I don't know how to put it -- a nerve-wracking situation,

Page 65

right? Because you have to anticipate it. You have to hope you see it. And if you don't, you're going to miss it.
BY MR. SLATER:
Q. Do you know -- well, rephrase. I think you've already said that you don't know and didn't apply any particular standards in terms of what the people at ZHP were supposed to do to try to anticipate potential genotoxic impurities; correct?
MS. ROSE: Object to the form.
THE WITNESS: No, I don't know what protocols they were supposed to do or -- I know what they did in the DIR afterwards, but not beforehand.
BY MR. SLATER:
Q. And you don't know what they were supposed to do based on any regulatory standards or any internal protocols. That's not something you took into account; right?
MS. ROSE: Object to the form.
THE WITNESS: That's correct, I did not take that into account.
BY MR. SLATER:
Q. In terms of what could have been known here, you base that on your own experience and

Page 66

knowledge from your own work. That was -- that was your criteria; correct?
MS. ROSE: Object to the form.
THE WITNESS: I based it on my knowledge and what I thought the knowledge would be for the people I worked with over the years, and also on the fact that this -- these amendments that the DMF were reviewed by chemists at the FDA and the EMEA. So I got insight into what they were thinking also from their responses to those amendments.
So it was three -- really three different things. It wasn't just my own opinion. It was -- I mean, there was people out there reviewing those documents with an eye towards safety who didn't notice this.
BY MR. SLATER:
Q. You agree with me that ZHP was responsible for the quality of its valsartan API at all times?
A. I agree that they were responsible for the quality and they were responsible for knowing the process. But when I say the FDA reviewed it and missed it, I'm not saying they were responsible. I'm saying they did it -- I could understand what they were thinking. That's all I'm

Page 67

saying, is what they were thinking, and they didn't see it. I'm not saying they were responsible. I'm just saying what they were thinking. That's all I'm doing with that information.
Q. In forming your opinion here, are you relying on statements by the FDA?
A. I wouldn't say -- I'm not relying on the FDA statements in a major way. I mean, in a supporting way, yes, there's a lot of statements the FDA made that support -- support my opinion that this was not an -- not an obvious and easy thing to catch.
Q. Do you know whether or not ZHP was expected to be aware of this risk even though it wasn't obvious and easy to catch, as you said?
MS. ROSE: Object to the form.
THE WITNESS: Do I know if ZHP should have been -- what exactly did you say?
BY MR. SLATER:
Q. I'll ask it again. Do you know whether ZHP was responsible to identify the potential risk of forming these genotoxic impurities even if it was not, to quote you, obvious and easy to catch?
A. I don't know the answer to that question.
Q. When you say that the FDA statements

Page 68

support your opinion, is that the statements that you quoted in your report regarding whether or not people were aware of the presence of nitrosamines in the valsartan drug product before it was disclosed in June 2018?
A. I'm not exactly sure. There was a -- you know, there was a statement that came out about the GC mass spec method they developed, and this was not easy to do because they're difficult to see. So it was statements like that that the FDA came out with that I thought supported the position that this was -- this was a difficult wrinkle to see.
Q. Did you also notice that the FDA issued a warning letter to ZHP and put them on an import alert?
A. Yes, I did.
Q. Did you see that the FDA was critical of ZHP's evaluation of this question of the potential impurities when they were developing this manufacturing process?
A. So --
MS. ROSE: Object to the form.
THE WITNESS: -- my recollection of that warning letter comes from Najafi's report. And when I read through each one of them -- there was

Page 69

like eight of them -- it didn't look to me like any one of those problems resulted in them missing this impurity. And there were other problems with, like, reporting structures.
And they were not -- there wasn't a single problem I saw in the warning letter that I could directly attribute to them not observing this impurity. So it was -- it was -- it wasn't -- it was irrelevant. I hate to say that their warning letter was irrelevant, but it was irrelevant to my forming this opinion.
Q. So I understand, you felt that the contents of the warning letter was irrelevant to the issue that you were opining on?
MS. ROSE: Object to the form. Misstates the witness.
THE WITNESS: Yes, it was irrelevant to the issue that I was providing an opinion on, yes.
BY MR. SLATER:
Q. Did you read the warning letter or just the account of it in Dr. Najafi's report?
A. I just read the account.
Q. Can you pull up the next exhibit, please? We're up to five now. We're going to put the warning letter in. Exhibit 5 dated November 29,

Page 70

2018.
A. That's Exhibit 5?
Q. Yes, that's what I'm told.
A. Okay. I see it.
Q. And you have never read this letter before right now; right?
A. I don't think so, no.
MS. ROSE: Hold on, Adam. Sorry. I'm unable to see the exhibit.
MR. SLATER: It's on the screen. Oh, you're saying in your --
MS. ROSE: Yeah. Sorry. Give me one second.
MR. SLATER: No problem.
MS. ROSE: I might have to reload it.
MR. SLATER: Hey, I can't criticize you, 'cause if somebody told me to go find it in chat or whatever, I couldn't do it if you put a gun to my head, so...
MS. ROSE: I have it now. Thank you.
MR. SLATER: Okay.
BY MR. SLATER:
Q. So Doctor, you can see this is the November 29, 2018 warning letter that was issued. And it's actually written to Mr. Jun Du, executive

Page 71

vice president of ZHP. Do you see that?
A. Yes.
Q. And by the way, we talked earlier. Were you able to refresh yourself as to whether Jun Du was the fourth person whose deposition you read?
A. I think he was, yes.
Q. If you go down to the second paragraph, it says, "This warning letter summarizes significant deviations from current good manufacturing practice, CGMP, for active pharmaceutical ingredients, API." Do you see that?
A. Yes.
Q. Then you already told me you're not giving any opinions on good manufacturing practices; right?
A. Right.
Q. Let's go to page, I think it's the fourth page of this letter. The Bates number in the bottom right is 42. It's paragraph number two.
A. Page on the right?
Q. Paragraph number two. It's the fourth page in. I was referring to the Bates number, the little numbers on the bottom right where the last two digits are 42.
A. Yeah, 62?

Page 72

Q. 42.
A. 42. Which page of the document? So there's a page number on the top of the document on the right. You see that?
Q. Yeah. It's page 4.
A. Page 4.
Q. Sorry about that. I had a Post-it note over that.
MS. ROSE: Just for clarification, I think the doctor was right. This Bates number ends in 62.
MR. SLATER: It does? Oh, it must be a different version of it. Okay. Sorry. You know what? Multiple versions. So...
THE WITNESS: That's helpful.
MR. SLATER: Okay.
BY MR. SLATER:
Q. Doctor, I'll start over. Looking now at page 4 of the warning letter, you see paragraph number two titled Failure to -- rephrase.
Looking now at page 4 of the warning letter, section two is titled, "Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API." Do you see that?

Page 73

A. I see that.
Q. This states, "In November 2011, you approved a valsartan API process change." And then in parentheses PCRC-11025 -- "that included the use of the solvent DMF. Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process, specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradents, including the primary DMF degradent dimethylamine." So I'm going to stop there. Do you see what I just read?
A. Yes.
Q. The information I just read to you you were not aware of before I'm reading it to you right now; correct?
MS. ROSE: Object to the form.
THE WITNESS: I don't know if this has showed up in any of the testimony that Najafi and Hecht gave, but okay, let's say I wasn't aware of it, yes.
BY MR. SLATER:
Q. You would agree that that statement by

Page 74

the FDA is significant; right?
MS. ROSE: Object to the form. He's not a regulatory expert, and said he can't comment on the FDA.
THE WITNESS: So this is another example of a hindsight, Monday morning quarterbacking comment, okay? So everybody knows after the fact where this -- there was a mutagenic and what it was and where it came from. So when they say you did not consider the potential for mutagenic impurities, it's -- it didn't -- it's -- it didn't present itself as something to consider. It's not that they didn't consider it. It never presented itself as something you should consider. So it still doesn't change my opinion.
BY MR. SLATER:
Q. You disagree with the statement by the FDA that ZHP failed to adequately assess the potential formation of mutagenic impurities when they implemented the new process, or is that beyond the scope of your opinion?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, I mean, it has to be beyond the -- I don't agree -- it's beyond -- it's really beyond the scope, because I don't know

Page 75

exactly what they did inside of ZHP to -- for the assessment. But it's -- it's beyond the scope, let's just say that.
BY MR. SLATER:
Q. This states in the next sentence, "You did not consider the potential for mutagenic or other toxic impurities to form from DMF degradents, including the primary DMF degradent, dimethylamine." Do you see that?
A. Yes.
Q. You have no reason to dispute that factual statement by the FDA; correct?
MS. ROSE: Object to the form.
THE WITNESS: So are you saying I don't dispute the fact of that statement?
BY MR. SLATER:
Q. You have no basis to dispute that factual statement by the FDA which they made after doing an inspection at ZHP; correct?
MS. ROSE: Object to the form.
THE WITNESS: I really can't answer that, because I don't know what they considered, but -- so you have to infer -- I would infer that if they thought of that happening, they would have investigated it. So they -- because they didn't

Page 76

think of it, they didn't do the investigation. So factually, I guess that sentence is probably true.
BY MR. SLATER:
Q. You said if they thought of it, they would have investigated it. Wouldn't the truer statement be if they thought of it, they would have been required to investigate it?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Let me ask it differently. If ZHP had realized the potential for mutagenic or other toxic impurities to form from DMF degradents, including the primary DMF degradent dimethylamine, they would have been required to investigate it; correct?
MS. ROSE: Object to the form. Outside the scope.
THE WITNESS: I believe it's both. They would have done it, and they would have been required to do it. They would have wanted to do it, and they would have been required to do it. Both.
BY MR. SLATER:
Q. You don't know whether they -- whether ZHP actually did evaluate that question at any point before June 2018; right?

Page 77

A. I do not.
Q. You agree with me that the primary DMF degradent is dimethylamine? You agree with me on that as a chemist; right?
A. I guess there's really two. If you're going to have dimethylamine around, you're going to have CO as well, and formic acid. So there's both.
Q. In your work over all the years that you've been a process chemist, did you ever work with DMF?
A. All the time.
Q. And were you aware that the DMF could include as an impurity dimethylamine?
A. I might have encountered that over the years, but it never enters into my mind when I suggest DMF as a solvent. I never think of it.
Q. That's your personal practice; correct?
A. And all the people I worked with.
Q. When you worked with DMF, did you familiarize yourself with the potential impurities that DMF could introduce to a manufacturing process?
A. When I did --
Q. When you worked with DMF, did you familiarize yourself with the potential impurities

Page 78

that the DMF could introduce to the manufacturing process?
A. No.
Q. In all the time that you worked with DMF, did you ever introduce DMF into a manufacturing process where it would come into contact with sodium nitrite or nitrous acid?
A. No. I don't believe --
Q. Have you ever or just --
MS. ROSE: I'm sorry, Adam. The witness wasn't done answering.
BY MR. SLATER:
Q. Not trying to interrupt. Go ahead.
A. I can't remember the last -- I think the last time I worked with sodium nitrite was 40 years ago in graduate school. Over 40 years ago. Almost never use it, not in pharmaceutical industry.
Q. Was that deliberate in the sense of trying to avoid a risk, or was it just that's how it went?
A. That's just how it went. It just wasn't a reagent that pharmaceutical chemists use. I think the raw material suppliers that supply our materials may use it, but we don't use it very much.

Page 79

Q. Why not? Why not use sodium nitrite?
A. Because the kind of chemistry we do, it doesn't call for the use of -- of sodium nitrite. It's just not -- it's not -- we don't need it for the synthesis.
Q. So that wasn't something that you had experience with in your active work; correct?
A. That wasn't something that I had what? I could probably turn the sound up a little bit.
Q. That's okay. So you did not have experience with the use of sodium nitrite in the processes that you worked with; correct?
A. That's correct.
Q. Just as a basic chemistry -- I'll come back to that. Let's go back to the warning letter, okay?
A. Okay.
Q. Second paragraph under heading number two says, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change." Do you see what I just read?
A. Yes.

Page 80

Q. And you see where the FDA pointed out that ZHP was required to ensure that unanticipated impurities were appropriately detected and controlled. Do you see that statement?
MS. ROSE: I'm sorry, are you reading from the document, Adam?
MR. SLATER: Yes.
THE WITNESS: Show unanticipated were probably detected. Yeah, I see that statement.
BY MR. SLATER:
Q. Your -- I think -- you can tell me if this is outside the scope of your opinion -- but you're not disagreeing with the FDA that ZHP was required to ensure that unanticipated impurities were appropriately detected and controlled? You don't disagree with that; right?
MS. ROSE: Object to the form.
THE WITNESS: I don't see how you can possibly do that. If you're not anticipating it and you don't know what you're looking for, how could -- how could you logically develop a method?
BY MR. SLATER:
Q. Let's go to the next sentence. The FDA said, "You are responsible for developing and using suitable methods to detect impurities when

Page 81

developing and making changes to your manufacturing processes." I want to stop there.
You see, that's the FDA's view is that that was required. You can see the FDA says that; right?
A. Yes.
Q. Is that outside the scope of your opinion in terms of whether that was required and how that applied to ZHP?
A. You know, when I read that, I -- I -- I read that as they had methods in place and they were using them to detect impurities. So I don't know -- I just don't know how you can expect them to come up with a method to detect something they don't know is there. I just don't know how that's practical -- how that's practical guidance.
Q. You're not offering opinions in terms of the risk assessment? You already told me that; right?
A. Yes.
Q. Do you have an opinion or is it outside the scope of your expertise as to whether the FDA is correct that ZHP was responsible for developing and using suitable methods to detect impurities when developing and making changes to their

Page 82

manufacturing processes?
A. It's outside of my scope. But my opinion is they were responsible, and they did it.
Q. Well, you told me you don't know what they did, actually; right?
A. Well, I know they used the methods from the monograph. What's that called, the US -- I know they did -- they had a method from the USP monograph. And they used it to detect impurities.
Q. Did you read --
A. I know they -- sorry. I know they did that much.
Q. Did you read the USP monograph?
A. No, I didn't.
Q. You don't have an opinion as to whether or not they complied with the USP; correct?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. That's outside the scope of your opinion; correct?
A. You know, I have an -- I think they followed the USP, but I don't -- didn't look at it. I don't know exactly what they did. I think they were following USP.
Q. Do you know what the USP required where

Page 83

ZHP changed the manufacturing process in terms of what ZHP was required to do at that point to test for potential impurities? Do you know what the USP required?
A. No.
MS. ROSE: Object to form.
THE WITNESS: Oh. Sorry. No, I do not.
BY MR. SLATER:
Q. So you don't know what standard would apply; correct?
A. That's correct.
Q. Do you understand what the chronology was of the various manufacturing processes that were used by ZHP to manufacture valsartan API were?
A. Do I understand the chronology?
Q. Yeah. Do you understand that there were several processes that were used in iteration?
A. Yes.
Q. Do you understand that the first process was called the tribunal team process?
A. Yes.
Q. Do you understand that process was not capable of creating nitrosamines?
A. I wouldn't say it was not capable. If you use sodium nitrite in the quench, you

Page 84

would -- you know, you might have got them, but -- okay, let's just say it was -- as conducted, it was not capable. Yes, actually, I don't think it was capable. I don't think --
Q. -- quenching; right?
A. Say that --
Q. -- process did not use sodium nitrite --
A. No, it did not. It did not. So it was not capable of performing nitrosamines.
Q. It was not capable of producing nitrosamines; correct?
A. Correct, unless you added that in.
Q. And then ZHP added sodium nitrite to the next processes that they developed, including the zinc chloride process; right?
A. That --
MS. ROSE: Object to the form.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. That was a change to the manufacturing process; right?
A. Yes.
Q. And the addition of DMF was another change to the manufacturing process that was added to the zinc chloride process; right?

Page 85

A. Yes.
Q. And you can see that the FDA in the second paragraph, under heading number two, talks about what the obligations of ZHP were when they made changes to the manufacturing process. That's what they're talking about there; right?
A. Yes.
Q. And in terms of what ZHP was expected to do in order to try to anticipate potential impurities, you're not in a position to tell us what they were expected to do or what standards applied; right?
MS. ROSE: Object to the form. Outside the scope.
THE WITNESS: Yeah, I can't really tell what they were expected. I don't really know the -- the regulatory requirements.
BY MR. SLATER:
Q. For example, you don't know what the regulatory requirements were for the level of scientific analysis ZHP was expected and required to perform in this context? You don't know that and you didn't apply that; correct?
A. Yeah, that's correct.
Q. Looking at this second paragraph, the

Page 86

last sentence of this second paragraph says, "If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients." Do you agree with that statement, or is that outside the scope of your opinion?

A. I agree with that -- that statement, but it is outside the scope.

Q. Let's look at the third paragraph. The FDA says, in the third paragraph here on page 4, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree.

"We remind you that common industry practice may not always be consistent with CGMP requirements, and that you are responsible for the quality of drugs you produce."

Do you see what I just read?

A. Yes.

Q. In your report you referred to industry practice several times; right?

A. Yes.

Q. And when you talked about industry

Page 87

practice, you were basing that on your own experience and the work that you did in your own labs; correct?

MS. ROSE: Object to the form.

THE WITNESS: Yes.

BY MR. SLATER:

Q. You didn't do a study or analysis of what other people were doing or what was being done across the industry, you based it on your own experience in your own work; correct?

A. Yes.

Q. Now, seeing that the FDA disagreed that pointing to current industry practice is adequate as a defense due to the failure to do this type of analysis, do you agree or disagree with the FDA, or is that outside the scope of your opinion?

MS. ROSE: Object to the form.

THE WITNESS: It's outside the scope. But again, as I said before, I don't see how you could practically comply with that. We remind you that common industry practice may not always be consistent with the GMP requirements. So then what -- what are you supposed to do? There's no guidance there as to what you are supposed to do. So it's -- it's a statement that really can't be

Page 88

complied with.

BY MR. SLATER:

Q. Based on your knowledge?

A. Based on -- yeah, based on common sense. How can you -- how -- what are you supposed to do -- what -- there's no reference to any guidelines that you should follow that will help you determine unanticipated unknowns. There's no -- there's no reference to anything like that.

Q. If ZHP could have known that the DMF could introduce dimethylamine either as an impurity of the DMF and/or as a degradation product of the DMF in the process, then you would agree ZHP had to take that into account; right?

MS. ROSE: Object to the form. Improper hypothetical.

THE WITNESS: So the introduction of dimethylamine is not the same as the introduction of NDMA. So you have to -- when he talks about extra dimension here, there's actually two dimensions, right? You have to recognize -- and dimethylamine is going to form, and then you have to recognize dimethylamine is going to react with sodium nitrite to form NDMA. You have to recognize those two things. So recognizing one alone is not

Page 89

enough to raise a red flag.

And I know in the depositions and the reports, you know, the red flag goes up, the alarm bells are going off, NDMA is forming, NDMA is forming. That's not true. That is simply not true. And I gotta take a bathroom break after -- after saying that. I'll be right back.

MR. SLATER: Go ahead. We'll wait here for you. We'll go off for a second and be right here.

THE VIDEOGRAPHER: We're off the record at 11:57 a.m.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 12:05 p.m.

BY MR. SLATER:

Q. We were talking about dimethylamine. So I want to ask you a few questions about that, okay?

A. Sure.

Q. Do you know what dimethylamine is?

A. I know the chemical structure of it, yes. I know what it is.

Q. What is it? Just how would you describe it?

A. I would describe it as ammonia with two

Page 90

methyl groups on it.
Q. It's known as a secondary amine?
A. It's a secondary amine, yes.
Q. Did you learn -- when did you first learn what DMA was?
A. I've probably -- it's not -- it's not a commonly used reagent, okay? It boils at seven -- it boils below room temperature. So you don't really use it for much. But dimethylamine, you know, people use. So I've known about it probably since undergrad. You know, over 50 years.
Q. I think you said before -- you can correct me if I'm wrong -- that when you worked with DMF, you would have been aware that DMA can be an impurity of DMF. It's actually one of the two primary impurities of DMF; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, that's not exactly what I said. I mean, you asked me if that would be a contaminant.
BY MR. SLATER:
Q. That's not what I asked, but --
A. What did you --
Q. I'm not trying to cut you off, but this is what I asked you.

Page 91

A. Okay. Yeah, let me -- let me -- I need to hear that again. Sorry.
Q. Would you -- and I'll try to ask it the same way I asked it before, but I'm going to add in the information you gave me in the answer so I can make it more correct.
A. Okay. That's fine.
Q. You mentioned formic acid when I asked the question.
Would you agree with me that the two primary DMF impurities/degradents are dimethylamine and formic acid?
MS. ROSE: Object to the form.
THE WITNESS: Yes. I mean, I've done -- I'm looking at this now for six weeks, so, yeah, I know that. And if you're sitting there having a discussion with me at the coffee table, I would say that. But I would never pick up a bottle of DMF and think those things are in there.
BY MR. SLATER:
Q. You agree with me, 'cause you talked to me about the importance of being aware of potential impurities, that when you worked with DMF, you were at least aware that that could potentially introduce dimethylamine into the manufacturing

Page 92

process. You at least would have needed to know that to take it into account; correct?
MS. ROSE: Object to the form, and misstates the testimony.
THE WITNESS: So unless I saw a peak, a peak on a chromatogram to rise from dimethylamine interacting with my substrate, I would never -- I would never think about it as being a problem. I have to see a peak to flag me. It's called a -- what would I call that? Instigation. Or it's a -- you just -- I have to see a peak. That's the triggering event, okay? That's the word. I see a peak, it's my triggering event. If I don't see a peak, I'm not thinking about it.
BY MR. SLATER:
Q. In the entire time you worked with DMF, though, you were aware -- I think you said this earlier -- that DMA was a potential impurity or degradent of the DMF? You at least told me you were aware of that; correct?
MS. ROSE: Object to the form. Misstates testimony.
THE WITNESS: I might have -- I might have heard of it and I -- I forgot about it. I mean, it's one of those factoids, it just

Page 93

doesn't -- doesn't stay unless it's continuously reinforced.
BY MR. SLATER:
Q. Am I correct that when you used DMF, you never did any independent research into the potential impurities or degradents of DMF?
A. No. If I used it and it worked in my reaction, I didn't look at the degradents. But you also have to be aware that everything that people use is less than a hundred percent pure. Every single agent is less than a hundred percent pure, and every single reaction doesn't give exactly one thing. So that's just common everyday occurrence.
Q. You would agree with me that anybody working at ZHP should have been aware of what you just said; right?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, I think chemists -- I think chemists generally know their materials are not a hundred percent pure and their reactions don't go to a 100.0 percent either.
BY MR. SLATER:
Q. If ZHP was aware of the potential that the DMF could introduce dimethylamine into the zinc chloride process, do you have any opinions as to

Page 94

what they needed to do in response to that, or is that outside the scope of your opinion?
MS. ROSE: Object to the form. Improper hypothetical.
THE WITNESS: That's outside the scope.
BY MR. SLATER:
Q. And it would be the same answer if I were to add into my hypothetical that ZHP, in the event they knew that dimethylamine could potentially be introduced to the process, either as an impurity or as a degradent of the DMF, and that they were using that in a process where it would be exposed to sodium nitrite or nitrous acid, what they needed to do in response to that, the answer would be the same, I assume, that's outside the scope of your opinion in terms of what they needed to do with that information?
MS. ROSE: Object to the form.
THE WITNESS: Yeah. I mean, I guess that's outside -- yeah, it's outside the scope.
BY MR. SLATER:
Q. Did you see literature among the materials you were provided by counsel indicating whether there was knowledge in the chemistry community that the combination of dimethylamine and

Page 95

sodium nitrite could create NDMA? Did you see any literature in the materials you reviewed indicating that?
A. Yes.
Q. For example, did you see in the IARC monograph on the evaluation of the carcinogenic risk of chemicals to humans from the 1970s that the IARC monograph indicated, "it has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic PH is in nitrosamine dimethylamine." Did you see that?
A. Yes, I did.
Q. And you would agree that the people at ZHP would have been expected to know that; correct?
A. No.
Q. And again, you're not able to tell us what, from a regulatory standpoint, ZHP's people were supposed to do to evaluate the potential reactions in the process? That's not something you're giving opinions on; right?
A. I'm not giving opinions on that.
Q. Do you agree with me that the information I just read to you was available to scientists in 2011 if they wanted to consult it?

Page 96

A. If they had a reason to search for it, they -- it was available. Yes, it was -- it's published with dates and page numbers. Yes, it was available if you wanted to find it. If you -- if you were looking for it.
Q. If you were looking for information about dimethylamine and how it might react with sodium nitrite, that information was available; correct?
A. If you wanted to find it, yes.
Q. And if you wanted to find information about what are the potential impurities that could be introduced by using DMF, you agree that information was available if somebody looked for it; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And that would include that if somebody wanted to research that issue of what -- rephrase.
If somebody actually did research one of the potential impurities that could have been introduced into the manufacturing process when we use DMF, you would agree that if somebody wanted to look at that question, that they could have learned that one of those impurities that could have been

Page 97

introduced was dimethylamine? That was available information in the literature; correct?
MS. ROSE: Object to the form. Improper hypothetical.
THE WITNESS: Yes, it was available.
BY MR. SLATER:
Q. You agree with me that if ZHP wanted to evaluate -- rephrase.
Are you aware of when ZHP got any -- any notice from anybody, whether internal to the company or outside the company, that there were peaks for the valsartan API manufactured by the zinc chloride process that were unidentified and of concern? Do you know when ZHP first became aware of that?
A. Yes. I saw that in the customer complaints. And I can't remember if that was in Najafi's report. I think it was. And I think the first one was probably 2014, and then 2015, 2016. Those are peaks in the GCFID trace, the residual solvent trace, yes.
Q. I didn't see any discussion in your report about what ZHP did or did not do with regard to the peaks showing on chromatography. I didn't see any opinions on that. Am I correct that's not

Page 98

something you're opining on?
MS. ROSE: Object to the form.
THE WITNESS: No. But, I mean, I -- from the deposition testimony I kind of -- I kind of know what happened there.
BY MR. SLATER:
Q. What I'm asking is -- you know what happened, but -- and I think you just confirmed -- you're not offering any opinions about what ZHP should or shouldn't have done in response to those peaks; right?
MS. ROSE: Object to form.
BY MR. SLATER:
Q. I didn't see any discussion of that in your report.
A. I didn't put any discussion in my report, but they responded to those requests.
Q. You're not offering any opinions about whether what they did was adequate or not? That's not something you've opined on; correct?
MS. ROSE: Object to the form.
THE WITNESS: No, I didn't put anything in my report. But I should -- I'll leave that one up to -- I mean, my understanding was the customers were satisfied with their response.

Page 99

BY MR. SLATER:
Q. But just to be clear, that's not something you offered any opinions on in your report about whether ZHP did an adequate evaluation of those unidentified peaks or not? That's not something that's addressed in your report at all; correct?
A. Yeah, that's not in my report.
Q. You do agree with me that GCMS and LCMS technology was available to ZHP throughout the time that they were manufacturing and selling the valsartan API; correct?
A. So from Min Li's deposition, I got it that the first LCMS was purchased at ZHP in 2013. So I don't think it was available while they were doing the process work.
Q. We have a PowerPoint which I can show you.
MR. SLATER: Can we pull it up, Chris? You know which one I'm talking about? All right. We'll come back to it then.
BY MR. SLATER:
Q. Let me ask you if you've seen this. Have you seen a PowerPoint from ZHP dated August 23, 2012 indicating that their research and development

Page 100

capabilities included an LCMS machine for mass spectrometry and Ajilent, A-J-I-L-E-N-T, 1100, and a GCMS Ajilent 7890A? Did you see that --
A. No.
Q. -- in the materials you reviewed?
A. No.
Q. You would agree with me that if ZHP wanted to utilize GCMS or LCMS going back to 2011, that technology was available and could have been used by them; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yes, it was available. But I remember from the Hecht deposition the question came up of how many USP monographs there are and how many compounds in that monograph use GCMS as a tool for residual solvent analysis, and it was something like four -- four compounds in the monograph out of 5,000 actually used GCMS. It's a very rarely used tool for residual solvents, especially in that timeframe.
So it's unreasonable to expect somebody to use a tool that's used one in a thousand times to pull that off the shelf and let's try it here and see what happens. That's just a -- not a likely or plausible scenario.

Page 101

BY MR. SLATER:
Q. Are you aware that before June 2018, ZHP was using GCMS and LCMS technology to evaluate impurities in their drug substance?
MS. ROSE: Object to the form.
THE WITNESS: You know, yeah, I guess from reading Min Li's deposition, that CEMAT -- CEMAT group that he built, I believe he bought -- he bought those instruments to look at -- to look at impurities in the new products they were developing, not going back retrospectively to look at existing products.
BY MR. SLATER:
Q. The technology was available for whatever purpose somebody wanted to use it for; correct?
MS. ROSE: Object to form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And you're aware that one of the uses for a GCMS machine is if you see a peak on regular gas chromatography and you can't identify it, GCMS technology can be used to actually identify what that peak is? That's one of the common uses of GCMS technology; right?
A. Right. But things that are below the

Page 102

reporting threshold you're not going to focus on. Those are going to be below the level at which you work on them. And below the -- the identification threshold would be a thousand PPM. So you would use GCMS if something was below -- above a thousand PPM, but you're -- you know, below 500 PPM, you don't have to report that.

Q. Are you aware of the regulatory standards that indicated that certain genotoxic impurities were of such concern due to their toxicity that the threshold did not apply to them?

MS. ROSE: Object to the form.

BY MR. SLATER:

Q. Yes or no, were you aware of that?

A. So the issue there is you have to know a peak is a genotoxic impurity. It's kind of a catch-22. So if you don't -- if it's below 500 PPM and you don't know it's a genotoxic impurity, you're not going to identify it. You have to know it's -- so you -- if you're using a genotoxic impurity and you see it there, and -- so this is what the guidance actually says. If you see a genotoxic impurity and you're looking for it, you see it, it's 50 PPM, you have to report that. But there is a gap in the guidance for things below 500

Page 103

PPM and above the level of detection.

Q. Are you telling me there's a guidance you can point to that says that if a cohort of concern substance, for example, an N-nitroso compound, has a peak, but you don't know that the peak is for the nitrosamine, you don't have to try to figure out what that peak is for?

A. No, that's not --

Q. -- ignore it because it's small?

MS. ROSE: Object to the form.

BY MR. SLATER:

Q. Is that your testimony?

A. That is not my testimony.

Q. Okay. That's what I was asking.

MS. ROSE: Can I just --

MR. SLATER: Wait.

MS. ROSE: Dr. Thompson, please let Mr. Slater finish his question before you give your answer, and also allow me time to object so we can spare the court reporter, please.

THE WITNESS: All right.

BY MR. SLATER:

Q. You're not suggesting that you need to know the answer before you start to look for the answer; right?

Page 104

MS. ROSE: Object to the form.

BY MR. SLATER:

Q. Let me ask the question differently. Withdraw the question.

This area in terms of what they needed to look for, is this outside the scope of your opinion?

A. Yes, it is.

Q. Okay. In terms of whether or how they should have used the technology, that's not something you're opining on, but you'll agree with me the technology, GCMS and LCMS, was available to ZHP if it wanted to use that technology from 2011 all the way through? You'll agree with me on that statement; correct?

A. According to the PowerPoint, they had those instruments -- they're saying they had those instruments sometime in 2012. So from that point on, yes, they had them there.

Q. And the technology was available even before that if they chose to obtain it or get access to it whether they owned it themselves or not; right?

MS. ROSE: Object to the form.

THE WITNESS: Yes, the technology was

Page 105

available if you -- if you saw a need to use it.

MR. SLATER: Why don't we -- I think this is a good time. You said you wanted to break around 12:30, and I think we're pretty much there, rather than me jumping into another document. So let's go off.

THE VIDEOGRAPHER: We're off the record at 12:25 p.m.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 1:35 p.m.

BY MR. SLATER:

Q. Doctor, I want to ask you a couple questions about a 2017 e-mail that you reference on page 6 of your report.

A. Okay.

Q. Did you read that e-mail written by Dr. Jinsheng Lin?

A. I read the translation.

Q. You state in your report, "It is difficult to interpret this e-mail." Why did you say that?

A. Yeah. I mean, so the e-mail, the body text and the patent that he references, is really about nitrosations of a sartan background -- of

Page 106

nitrogen and a sartan background. So it's really about nitrosations of the API or the deacylated API. So that's the whole topic. That's the attachment.

And then out of the blue comes this sentence, you know, similar to the NDMA found in valsartan. It's kind of a non -- it's a non sequitur. So, I mean, quite honestly, I thought it was poorly interpreted. I just thought my interpretation was wrong, and that those words weren't right -- weren't a perfect interpretation of what was written in the e-mail.

And, you know, I don't have much of a basis for saying that. It's just that it's -- it's just a non sequitur. There's no backup data in addition to that one sentence. So I had a little difficulty with it.

And then I guess I finally decided that the interpretation that probably fits all the data is that he's trying to, you know, calibrate this team. This is how important I see this issue for the company. So it's similar to a situation where we have NMDA in valsartan. You know, that's -- that's where I put this issue in terms of importance for things you should think about.

Page 107

So, you know, that's kind of the basis for that statement it's difficult to interpret.

Q. You know, I assume you don't read or write the Chinese language; is that correct?

A. I do not. I don't even take Chinese cash.

Q. Did you read -- you mentioned that -- rephrase.

You mentioned that you read two of the days of Min Li's deposition. Do you recall if you read the day where he was asked about this e-mail?

A. Yeah, I did.

Q. Do you know who Min Li is?

A. I don't know exactly his position at the company. He's like a director of -- I think he's the guy -- the top man in charge of the analytical department at ZHP. That's what I think his job is.

Q. Do you understand that he actually is the person that Jinsheng Lin reported to?

A. Yes.

Q. And did you see that we asked Min Li about the e-mail and he testified to what the e-mail said?

MS. ROSE: Object to the form.

THE WITNESS: Yeah, Min Li's responses

Page 108

were uniformly the company didn't know. That's not -- that's not what he said. The company didn't know. Uniformly, every time he was asked a question about that e-mail, that's what his response was. Every time. That's what I remember his response being. Yeah.

BY MR. SLATER:

Q. You don't recall in the deposition of Min Li when I walked through with him the entire e-mail and what it said?

A. So, you know, I can't -- I don't recall every word that was said, but my general impression of what he said -- I looked back at it recently, a day or two ago, and generally what he was saying is the company did not know. Every time he was asked the company knew, and his response was the company did not know. It was this one guy who had a theory.

Q. Do you know what Jinsheng's -- I'm sorry. Do you know what Jinsheng Lin's job was?

A. Again, I'm going to assume what it was. First of all --

Q. I'm asking if you know what his job was.

A. No, I do not. Oh, yes, he was -- he worked in the CEMAT group. He did something in the

Page 109

CEMAT group.

Q. Do you know what he did in the CEMAT group?

A. Not exactly. Seemed like a bunch of things.

Q. Do you know that he was in charge of the group that was responsible to identify the root causes of impurities seen in drug substance?

MS. ROSE: Object to the form.

THE WITNESS: I assumed he was in that group, yeah, that identified impurities, yeah.

BY MR. SLATER:

Q. And you understand that Min Li was the head of CEMAT; right?

A. Yes.

Q. Do you recall Min Li saying that he doesn't recall seeing the e-mail because he gets a lot of e-mails and he doesn't recall seeing it?

A. That's right, he did -- he did say that. So then all --

Q. I'm just asking if you remember him saying that.

A. Huh?

Q. I'm just asking if you remember him saying that.

Page 110

A. Now that you bring it up, yes, I do remember that, yes.
Q. Do you remember him confirming that as part of the e-mail, the e-mail states that what was being seen in its irbesartan product they were working with is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite?
MS. ROSE: Object to the form. Are you reading from a document?
MR. SLATER: I'm reading from the translation that is cited in the reliance list by your expert, by Dr. Thompson.
MS. ROSE: Okay. You're asking --
MR. SLATER: The question --
MS. ROSE: -- something he's not looking at?
MR. SLATER: I'm not sure why that's funny, but I'll continue. I'll ask a new question.
MS. ROSE: I wasn't --
MR. SLATER: Let's --
MS. ROSE: -- addressing anything as funny.
BY MR. SLATER:
Q. Let me ask you this, Doctor. New question.

Page 111

Do you remember Min Li testified to what the e-mail said?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Do you remember -- I'll ask it differently.
Do you remember Min Li having the Chinese language version of the e-mail in front of him, and walking through the e-mail and testifying to what it said? Do you recall that happening in his deposition?
A. I remember reading that in the deposition. I don't remember every word of every response, but I remember that he was walking through it.
Q. And do you recall that as part of that he agreed that the e-mail said words to the effect of that what was being seen in this irbesartan substance they were working with was similar to the NDMA that occurs in valsartan as a result of the sodium nitrite quenching? Do you recall that was part of what he said the e-mail stated?
MS. ROSE: Object to the form.
THE WITNESS: I don't exactly recall. I don't exactly recall that. He might have said it.

Page 112

I just don't recall it.
BY MR. SLATER:
Q. We're going to put up as the next exhibit -- what are we up to, six, now? Exhibit 6 is going to be the e-mail, which is ZHP00190573, which is listed in your list of materials reviewed as one of the documents that you reviewed.
A. Okay.
MS. ROSE: Is this Exhibit 7?
MR. SLATER: This is I think six, I was told by Chris.
MS. ROSE: Oh, apologies.
MR. SLATER: I mean, we'll stand to be corrected if it's seven, but...
MS. ROSE: No, it's fine. I have six. I thought seven -- I thought there was a seven that hadn't popped up yet. But I've got it at six. Okay, I got it.
BY MR. SLATER:
Q. First of all, you've read this; right?
A. Yes.
Q. Let's look -- looking at the first page of the document -- let's go scroll -- perfect.
In the first -- first paragraph you can see it's written to someone saying -- someone

Page 113

named Jucai Ge. Do you see that?
A. Yes.
Q. Do you know who that is?
A. So I didn't know -- you know, when I wrote the report, I didn't know. But then when I read the deposition, I could see Min Li describing who all these people were and what their job titles were.
Q. It's people --
A. So I --
Q. -- pretty high level people in the company; right?
A. Yeah. That's why I thought it was kind of strange that he was writing a chemistry e-mail to all these executives with all this chemistry, mass specs and reaction mechanisms, to all these high level people, and none of them are chemists. I was like, that's a little odd. You know, I could -- I don't know if any of them actually read it. But I looked at it and said this is not in my wheelhouse and closed it. That's -- that's what I thought.
Q. You thought none of these people were chemists?
MS. ROSE: Object to the form.

Page 114

THE WITNESS: I was -- I was -- I didn't know all eleven of them or how many of them. But there was a QA person. There was a regulatory affairs person that Min pointed out. There was analytical people. It didn't mention the name of one single chemist, synthetic chemist in process chemistry on that list.

It might have been 'cause I didn't read every one, but I was surprised at their job functions in relation to what this e-mail was about. I was -- why would he send to those people. But, okay.

BY MR. SLATER:

Q. Do you know what Min Li's background is?

A. Min Li?

Q. Yeah, Min Li. He's on the --

A. Yeah, he's an -- he's an analytical chemist. Johns Hopkins. Then he went to Schering. Then he went to Merck. He went back to Schering. I saw that because my wife worked at Schering, I worked at Merck. And then Merck acquired Schering, so he went back to Merck. Hey, got a pretty good pedigree. Analytical chemistry.

Q. In the first paragraph of this e-mail, the last sentence says, "However, after the

Page 115

improvement there is an unknown impurity of about 0.544 percent at 26 minutes in the crude irbesartan, and is the largest impurity in the irbesartan crude product." Do you see that?

A. Yes.

Q. And then the next paragraph, the third line -- the second and third line, he says, "Based on the test results of these two days, currently it can be confirmed that the impurity is a nitroso derivative of the irbesartan." Do you see that?

A. Yes.

Q. So certainly by July 2017 we have documentation that ZHP was aware that in this process for developing a sartan, a nitroso compound was being produced? That's what this sounds, right?

MS. ROSE: Object to the form.

THE WITNESS: This plays exactly into how --

BY MR. SLATER:

Q. I'm just asking if that's what it says, sir.

MS. ROSE: Please let him explain his answer. He's answering your question.

THE WITNESS: This is how impurities are

Page 116

identified. You see an unknown peak. You figure out what it is, and you work your way backwards to how it happened. This is exactly an example illustrating the process of impurity identification. If you don't see a peak, you're blind. He saw a peak. He figured out where it was. He figured out where it came from. And he figured out what to do with the process to fix that.

BY MR. SLATER:

Q. So an unknown peak, right, didn't know what it was at first, and then had to investigate it; right?

A. Yeah, because he saw it. He saw it. It was there on the chromatogram. The biggest peak as well. It was -- it was -- that's the kind of thing the FDA is saying in all their guidance. You see a peak, you identify it. You don't ignore a peak. That's what they're saying in their guidance, and that's what they did.

Q. Coming back to the question I asked. I'm just asking. He saw an unknown peak and investigated it; correct?

A. Yes.

Q. And then let's go to page 2. At the very

Page 117

top, he says, "Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO compound." Do you see what I just read?

A. Yes.

Q. So first of all, we know that he evaluated this unknown peak using mass spectrometry; right?

A. He had a trigger to do that evaluation, yes.

Q. I didn't ask you about a trigger, Doctor.

A. I answered your question. I said yes.

Q. Okay. Let me ask it again, and we'll just -- what I'm going to ask of you, to the best of your ability, is if you could try to answer just the question I ask and not talk about something else as well, 'cause I'll -- 'cause I'm going to keep coming back and we'll just make it go faster. And as I told everybody, I cut out a bunch of stuff before to try to move it along, but if we start to now go through other things when I ask a question, I'm going to have to keep coming back. It'll take longer.

MS. ROSE: Adam, please don't direct the

Page 118

witness how to answer your question.
MR. SLATER: I think I was about to --
MS. ROSE: He's answering --
MR. SLATER: -- not interrupting, Nina. So, please.
MS. ROSE: Well, please don't direct the witness or suggest to the witness that he's not answering your question. He is answering your question.
MR. SLATER: Okay. So if I ask what color the light was and somebody starts telling me about how a car drove, and then at the end says yeah, but the light was red, you think that's responsive? You don't have to answer that. But that's what just happened. And I would appreciate if we don't have that happen all day.
MS. ROSE: Object to the characterization.
MR. SLATER: I really will go to ten o'clock if we're going to start this now.
THE WITNESS: Okay. I'll do my best.
MR. SLATER: Thank you. I appreciate it.
BY MR. SLATER:
Q. Looking at the top of page 2, one thing we know is that this Dr. Lin in CEMAT in July of

Page 119

2017 used mass spectrometry to identify an unknown peak; correct?
MS. ROSE: Object to the form. Already asked and answered.
BY MR. SLATER:
Q. That's what happened; correct?
A. Yes.
Q. And he concluded it's very likely it is an N-NO compound, meaning a nitrosamine; correct?
A. Yes.
Q. He then states, "It is similar to the N-nitrosodimethylamine" -- and that's NDMA; right?
A. Yes, it is.
Q. -- "that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic." That's what it states here; correct?
A. Yeah. I thought that was a quasi-ignorant statement. But yes, that's what it says.
Q. I have to ask the question again, 'cause I didn't ask if it was a quasi-ignorant statement. So now I have to ask it again, Doctor.
A. I'm going to have to go to the bathroom.
Q. I don't care. You can go to the bathroom as much as you want. But every time you do that,

Page 120

I'm going to ask the question again.
MS. ROSE: Okay. Please don't badger the witness, Adam.
MR. SLATER: I'm not badgering him. I think I've been as polite as possible. And I'm not going to ascribe any motives, but I'm just saying I didn't ask if it was a quasi-ignorant statement, so...
BY MR. SLATER:
Q. So let me ask it again. This says, in the next sentence, "It is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic." That's what it says; right?
A. Yes, that's what it says.
Q. And as was stated a moment ago, N-nitrosodimethylamine is NDMA; correct?
A. Yes.
Q. He says that the NDMA occurs in valsartan; right?
A. Yes.
Q. And he says it occurs in valsartan when quenched with sodium nitrite; correct? That's what the words on the page say; right?

Page 121

A. That's what the words on the page say.
Q. And you know, as you sit here right now, that the NDMA that formed in the valsartan occurred due to the sodium nitrite quenching. That's a correct statement of the root cause; correct?
A. Yeah, I just -- it's just -- that sentence is completely out of context with the rest of the e-mail.
Q. My question is this: The statement that the NDMA occurs in valsartan when quenched with sodium nitrite is an accurate statement and accurately states the root cause for the formation of NDMA in valsartan. You know that as you sit here right now; correct?
A. So --
MS. ROSE: Object to the form.
THE WITNESS: -- my first impression when I read this was it was not -- the English -- whoever did the interpretation got it wrong. I didn't believe those words. I see them there, but I don't -- I didn't believe them.
BY MR. SLATER:
Q. So your opinion is that those words just don't belong there and you can't explain where they come from, so you just are negating them and

Page 122

setting them aside and not taking them into account in your opinion? That's a yes or no question.
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Do I understand you correctly?
A. I'm trying to get them to fit.
Q. Okay. Let me come back. The reason you're having trouble getting them to fit is because you can't believe that somebody at ZHP knew that there was NDMA in valsartan and what the root cause was in July of 2017, and nobody said anything to the public about it? That's the problem you're having with this, is how could they know this and not tell anybody? That's the issue; right?
MS. ROSE: Object to the form.
THE WITNESS: The issue is it's out of context and there's no backup data. There's no data to support that. I respect data.
BY MR. SLATER:
Q. Did you ask the lawyers who retained you, hey, what's the background behind this document? Did you ask them that question?
A. We talked about it a little -- yes.
Q. Okay. Did you know or did you learn that this document was produced to us as a PDF off of

Page 123

Min Li's laptop, and that nobody else who received it was listed as a duplicate custodian, suggesting that we were never supposed to see the document? Were you aware of that?
MS. ROSE: Object to the form. Object to the characterization.
BY MR. SLATER:
Q. I'm asking if you were aware of that, that that's what we're asserting in this litigation and have asserted in open court.
A. So I don't know what --
Q. Is that yes or no?
A. I don't know what a duplicate custodian means. I don't know what that term means.
Q. Duplicate custodian means that every single person that received this e-mail -- and we talked about the long list before -- every one of them, when it was produced to us, there's something called metadata, and it's supposed to list every person that got it so that we know, okay, we didn't produce it ten times to you, but it went to all these people and was in their files when the documents were produced.
Did anybody ever tell you that, that they were -- it actually was never disclosed to us

Page 124

in the metadata that all these other people got it?
MS. ROSE: Object to the form. Object to the characterization. Object to discussions of discovery issues.
MR. SLATER: Your objection is noted.
BY MR. SLATER:
Q. Can you answer the question, Doctor?
A. Yeah, no one told me that. I didn't ask.
Q. Okay. If -- all right. So let me come back to what I actually was trying to ask you before we went down this side road.
The statement that there's NDMA in valsartan, and the root cause is the quenching with sodium nitrite, is a true and accurate statement of the root cause for the NDMA formation in the valsartan. You know that as you sit here right now; correct?
MS. ROSE: Object to the form.
THE WITNESS: That's what -- yeah, that's what the deviation investigation says, and that's the theory, yes.
BY MR. SLATER:
Q. And you agree with that; right?
A. Yes.
Q. So it's not just that he said there's

Page 125

NDMA in valsartan, he actually noted the root cause for it; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yeah. And I heard his boss say nobody at the company knew in the deposition.
BY MR. SLATER:
Q. What you heard the boss say is I don't remember seeing the e-mail. That's what you remember him saying under oath; right?
MS. ROSE: Object to the form.
MR. SLATER: Why are you objecting?
MS. ROSE: You're putting words --
MR. SLATER: What's the basis for that objection?
MS. ROSE: You're misstating his prior testimony completely.
MR. SLATER: No, I'm not.
BY MR. SLATER:
Q. You can go ahead, Doctor.
A. Two different things. They didn't see the e-mail. No one at the company knew. He didn't have to see the e-mail to know that no one at the company knew.
Q. Did it ever occur to you --
A. -- putting those two together.

Page 126

Q. Okay. Rephrase. When you were evaluating this e-mail, did it occur to you that maybe the people at ZHP didn't want to admit under oath that there were people in the company that knew there was NDMA in valsartan in July of 2017? Did that occur to you that maybe they didn't want to admit that they knew about this and didn't tell the world because of how massive of a regulatory violation that would be?

MS. ROSE: Object to form.

BY MR. SLATER:

Q. I just want to know if you took into account that possible explanation.

A. If I took that into account, I wouldn't -- I wouldn't use it because it's a total speculation on their behavior that I have no reason to -- no basis to support.

Q. Well, you're speculating that this -- that this sentence just somehow magically got into the e-mail by mistake. Isn't that speculation?

MS. ROSE: Object to form.

THE WITNESS: The sentence is complete -- sorry. The sentence is a complete non sequitur, so I can't fit it in the rest of the topics.

Page 127

BY MR. SLATER:

Q. Actually, the sentence makes perfect sense. And I'll tell you why. And you tell me if you agree. Let me ask the question differently.

He is characterizing this nitrosamine he's seeing in this irbesartan substance they're experimenting with, and compares it to another nitrosamine that he states they know occurs in valsartan and is caused by sodium nitrite. So he's actually comparing what they're seeing here in the irbesartan to something they know exists in the valsartan, and then says, "and its structure is very toxic."

That makes sense. That's what you would expect a chemist to do, is say this looks like something else we already know exists. That makes sense, doesn't it?

A. So all of those -- that and nitroso and impurity K are N-nitrosos on the sartan backbone, and NDMA is a completely different molecule. No, the comparison does not make sense.

Q. Okay. I would like you to assume that Jinsheng Lin actually intended to write into this e-mail what he wrote, okay?

Well, let me ask you this. Let me withdraw that.

Page 128

You have no information, no basis to say that that phrase in that sentence that we're talking about, "It is similar to N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic," you have no basis to say that that sentence was not intended to be in this e-mail; correct?

A. The basis I have is that it's a non sequitur with all the other topics.

Q. Isn't it possible that this person who was an expert at evaluating impurities in drug substance was comparing this impurity he was seeing in this irbesartan substance to an impurity he knew existed in valsartan? That's possible; right?

A. He would be comparing it to impurity K, not to NDMA.

Q. He doesn't say impurity K. He says NDMA; right?

A. He -- he attaches a patent that talks about --

Q. That's later in the e-mail.

MS. ROSE: Please --

BY MR. SLATER:

Page 129

Q. I'm talking about this sentence.

MS. ROSE: Mr. Slater, please do not cut off the witness when he's in the middle of an answer.

MR. SLATER: I'm not really sure if there's an answer, or what's going on.

BY MR. SLATER:

Q. Doctor, you want to talk about impurity K. That gets mentioned at the bottom of the e-mail; right? Actually, impurity K doesn't even get mentioned. There's a reference to a patent at the bottom of the e-mail.

A. And in the patent -- in the patent it talks about impurity K. The whole topic is about nitrosations on the nitrogen atom of the sartan backbone, not on the nitrosation of a completely different molecule.

Q. Let's take the phrase, "It is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite."

You'll agree with me that based on that, on its face, Jinsheng Lin knew that there was NDMA in valsartan, and it was formed as a result of sodium nitrite quenching. And he knew that as of the day he wrote the e-mail. If you take it on its

Page 130

face, whether you think that sentence belongs in the e-mail or not, he knew that; right?
A. You can interpret it however you want. I don't interpret it that way.
Q. So you think he said that and it was just a massive coincidence that he mentioned something that happened to be absolutely true at the time, and you think it's just complete coincidence that it got in there in some kind of happenstance of fate?
A. Yes.
Q. Do you think it was a massive wild guess?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Let me ask this. Let me withdraw that.
This guy's job was to identify impurities and the root cause for impurities; right?
A. Yes.
Q. And that's what he's talking about in that phrase, "NDMA is in valsartan, and the root cause is sodium nitrite quenching." That's what his job is, is to say things like that; right?
MS. ROSE: Object to the form.
THE WITNESS: I think he was pointing

Page 131

out -- I said it's my -- he was pointing out this would be a problem of a similar magnitude of NDMA forming in valsartan from sodium nitrite. If you look at the list of all the cohort of concerns, the first one on the list is always NDMA. He pulled the first one off the list and used that for his comparison. I gotta take a leak. Can we -- is that okay?
MR. SLATER: Sure.
THE WITNESS: I mean, do you want to go on, or --
MR. SLATER: No, we can take a break. You go to the bathroom and come on back.
THE WITNESS: Okay. Thank you. Be right back.
THE VIDEOGRAPHER: We're off the record at 2:03 p.m.
(Break taken.)
THE VIDEOGRAPHER: Back on the record at 2:05 p.m.
BY MR. SLATER:
Q. Let's go down to the paragraphs underneath the diagrams. The second paragraph under the diagrams, it says, "If it is confirmed as the above-speculated structure, then its toxicity

Page 132

will be very strong and there will be an extremely high GMP risk." Do you see what I just read?
A. Yes.
Q. He then states, "This is a common problem in the production and synthesis of sartan APIs." You see that?
A. I do.
Q. And you know as you sit here right now that multiple sartans turned out to have this exact problem due to sodium nitrite quenching. You know that as you sit here right now; right?
A. I know of two sartans where nitrosations of the sartan backbone is a problem from sodium nitrite. I know of two.
Q. Which two do you know about?
A. Irbesartan and impurity K.
Q. What about valsartan?
A. Valsartan is a deacylated version -- I mean impurity K is a -- comes from a deacylated version of valsartan. So that's -- that's -- that's the nitrogen that I'm talking about when I say impurity K getting nitrosated. Not clear? I know of two. You asked me if it's a common problem, and I said I know of two.
Q. So you're drawing a distinction where

Page 133

something's deacylated?
A. If it's not deacylated, it's not going to form an N-nitroso compound.
Q. So are you aware that N-nitroso compounds formed in valsartan, irbesartan, and losartan?
A. I don't know about losartan. I've never seen one.
Q. Okay.
A. But I don't know about that. That's why I said I only know of two.
Q. One possibility is that Jinsheng Lin knew, as of July 27, 2017, that NDMA was occurring in the valsartan that ZHP was manufacturing and the root cause was the sodium nitrite quenching? That is possible from this e-mail; correct?
A. That's a possibility.
Q. Let's go down now to the last paragraph. After the whole discussion in the e-mail, at the very end Jinsheng Lin says, "I've also attached a patent of a 2013 sodium azide NaClO quenching method by Zhejiang's Second Pharma Company Limited. They proposed that the use of NaNO2 quenching" -- that would be sodium nitrite quenching; right?
A. Right.

Page 134

Q. -- "will result in the formation of N-NO impurities"; right?
A. Yes, that's what it says.
Q. So let's stop there. Did you read the patent?
A. I did.
Q. And that patent was from 2013; right?
A. Yes.
Q. And did you see in the deposition testimony that that patent was in ZHP's files as of 2014?
A. I think I remember seeing that, yes.
Q. And therefore ZHP was aware, at least as of 2014, if not earlier, that sodium nitrite quenching will result in the formation of nitrosamine impurities; right?
A. Impurity K.
Q. That's not what this e-mail says, sir. So I'm asking you what it says.
A. Well, that's what it implies. Everybody knew about impurity K.
Q. Is impurity K --
A. That --
Q. -- a nitrosamine?
A. That paragraph does not imply --

Page 135

THE WITNESS: Nina, you want to talk? Nina, you're on mute. Can't hear you.
MS. ROSE: I apologize. Hopefully my objections have been coming through. But you've been cutting off the witness. Please let him answer the question.
THE WITNESS: My feelings aren't hurt. So that paragraph doesn't say anything about NDMA. That's not what it talks about. It's talking about impurity K. It's talking about -- it's talking about impurity K.
BY MR. SLATER:
Q. Let's look at what this scientist, whose job it was to determine the root causes of impurities, what he actually said in the e-mail. Can we do that?
A. Sure.
Q. You've never spoken to Jinsheng Lin; right?
A. I have not.
Q. So let's look at his actual e-mail. His e-mail says that this other company, Zhejiang Second Pharma Company, proposed that the use of sodium nitrite quenching will result in the formation of nitrosamine impurities. That's what

Page 136

the language says in the e-mail; right? Is that what the e-mail says?
A. Yeah, when you look at the patent, it talks about impurity K.
Q. Now I have to ask the question again.
A. Okay.
Q. I'm going to make a promise to you. We're going to talk about the patent. I don't have any idea why you-all think that patent helps you, but we'll talk about it, okay?
MS. ROSE: All right. Object to the characterization.
MR. SLATER: I don't know why it keeps getting thrown in, so I get to a characterization --
THE WITNESS: I think it --
MS. ROSE: He's trying to answer your question.
THE WITNESS: I think it clarifies, you know --
BY MR. SLATER:
Q. I didn't ask you to clarify it, though. I just asked you what the document said.
A. So are you saying I can't clarify statements?

Page 137

MS. ROSE: I apologize. Please do not cut off the witness and not badger the witness. He can -- ask your questions. He's answering your questions.
BY MR. SLATER:
Q. Right. Let's try to answer my questions. If I want clarification, I'll say by the way, give me clarification. I'm just asking simple questions. If I ask you what the document says, I'm not sure why you're explaining something else. That's my question to myself. Why is he talking about this other thing? I just asked him this. That's where my consternation comes from.
A. Well, the question is implying --
Q. No, it's not, actually.
MS. ROSE: Again, Adam, please stop cutting --
MR. SLATER: There's not even a question pending, Nina. I explained to him why I was getting frustrated. I'm being very nice and polite. We like each other. He's a nice guy. I like Dr. Thompson. We're both doing our jobs. But I'm just explaining, and he's just starting to explain something else. There wasn't even a question. So I'm allowed to say hey, let me get to

Page 138

the next question.
MS. ROSE: You're just making speeches on the record then if you're not asking questions, which I think is unfair to the witness and extending this process more than it needs to.
MR. SLATER: Okay. All right. Well, I appreciate that. And I agree with you. This is -- we don't need any of this. What we need is to ask a question and answer a question. So I'm going to try it.
BY MR. SLATER:
Q. He says that this other company proposed that the use of sodium nitrite quenching will result in the formation of nitrosamine impurities; correct? That's the words on the page?
A. Yes.
Q. And in the patent it talks about the formation of a nitrosamine impurity called impurity K; right?
A. Yes.
Q. So as least as of 2014, if not earlier, at least Jinsheng Lin was aware that another company had figured out that sodium nitrite quenching could result in the formation of a nitrosamine impurity in valsartan. In the case of

Page 139

the patent it described impurity K. True statement?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. That's correct; right?
A. So the -- impurity K and NMDA are worlds apart. They're not the same thing. If I see impurity K, I'm not thinking NMDA. Two different planets in terms of structure and how they come about. That's my clarification.
Q. You agree with me that sodium nitrite quenching causes the formation of nitrosamine impurities in valsartan; right?
A. The way they ran the -- yeah, according to item four it did, yes.
Q. Let's go to the next sentence in this paragraph. The second sentence says, "At the same time, they" -- meaning this other Chinese pharmaceutical company -- "used ZHP's crude valsartan in their LCMS test and detected this impurity." Do you see that?
A. Yes, I do.
Q. So it's saying that this other pharmaceutical company in China, at least as of 2013 when the patent was dated, used LCMS, mass

Page 140

spectrometry, to identify the impurity; correct?
MS. ROSE: Object to the form.
THE WITNESS: Identified the impurity -- sorry. Sorry, Nina. Sorry.
MS. ROSE: Go ahead, Dr. Thompson.
THE WITNESS: Identified impurity K. Yes, they did.
BY MR. SLATER:
Q. Okay. So you'll agree with me that in China, at least, we know that pharmaceutical companies, when they couldn't identify an impurity, could and did use mass spectrometry to identify what those impurities were. That's what this is showing us; right?
A. Yeah, when they saw the peak, they were triggered to use LC mass spec, yes.
Q. And that's because a company should never ignore -- well, forget it. I'm not going to go there because -- I'm not going to go there.
A. You were going say to say they shouldn't ignore what they can't see?
Q. No, I actually wasn't going to say that. But we'll move along.
A. Okay.
Q. Let's look at the last two sentences of

Page 141

the e-mail. This indicates that other companies have paid attention to the quality problem very early on. You see that?
A. Yes.
Q. The quality problem is the formation of nitrosamine impurities due to sodium nitrite quenching. That's what he's talking about in this e-mail; right?
A. Yeah, the quality problems in impurity K. Or this one irbesartan. Yes, that's a quality problem.
Q. He also mentioned up above in the e-mail that what was being seen in the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite, which he said -- rephrase.
He also said above that what was seen in the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite. He also said that in the e-mail; correct?
A. Yes, he said that.
Q. And in the last sentence, after pointing out this quality problem, he says, "So leaders, please pay attention to this issue." You see that sentence?

Page 142

MS. ROSE: Object to the form.
THE WITNESS: Yeah.
BY MR. SLATER:
Q. Remember you asked me at the beginning of the deposition -- or you stated out as a question sort of to the world -- rephrase.
You remember at the beginning of the deposition you questioned why would he send this e-mail to all these high level people in the company? Remember you said that?
A. Yeah.
Q. Well, now you see at the end he says, "So leaders, please pay attention to this issue," the issue being a quality problem that other companies have noticed. Do you see that?
A. So none of those people can take -- can do anything about it. They're not process chemists. They can't make a change. All they can do is say why am I getting this e-mail.
Q. Couldn't they also say, hey, this guy's pointing out to us a quality problem we have with the manufacturer of our sartans, and he's literally telling them to beware because other companies are catching on to this problem?
MS. ROSE: Object to form.

Page 143

BY MR. SLATER:
Q. That's a responsible thing to do when your job is to identify impurities in a drug substance that your company's manufacturing. If you see a dangerous problem, you let the people at the top of the company know, hey, we have an issue we need to take care of. That's responsible; right?
MS. ROSE: Object to the -- Dr. Thompson, give me one second. Object to the form. Object to the speech.
THE WITNESS: I totally disagree. His responsibility, if he thought that, was to get in touch with the head of process research and say we've got a problem here. This is a chemistry problem. Let's take care of it, instead of sending it to a quality control person who doesn't have any control over what happens in the chemistry and their reactors. He sent it to the wrong people.
BY MR. SLATER:
Q. Well, he sent it to his boss, Min Li; right? He is that -- one of the people, right, who got it?
A. Yeah. No chemists. No process chemists. It's weird. That's weird.

Page 144

Q. He sent it to Peng Dong, who's the head of the analytical department, right? The technical department, I mean.
A. No analytical chemist tells a synthetic chemist how to run their reactions. It's ridiculous.
Q. You have Lihong Lin. She was the head of regulatory for the whole company. Did you know that?
A. Yeah. As -- again, I never saw a regulatory fast person walk into the process lab and say run your reaction differently. That never happened.
Q. Dr. Thompson, do you realize what happened when the world found out that there was NDMA in the valsartan?
A. Yeah, they immediately recalled it.
Q. It was a big problem; right?
A. Yes. They -- they reacted responsibly. They immediately recalled it.
Q. And that was because, as Jinsheng Lin described it, toxicity would be very strong and an extremely high GMP risk; right?
MS. ROSE: Object to the form. Object, outside the scope.

Page 145

BY MR. SLATER:
Q. Or is that beyond your scope of your opinion?
A. Well, when I look at the N-nitroso compound from irbesartan, that's not a risk. That doesn't look like a toxic compound. So he's being a little ignorant in his evaluation of what -- he sees N-NO and says toxic without any depth of understanding.
And I also read from Min Li's deposition that impurity K was qualified at a thousand -- at a thousand PPM by Novartis. So he's -- he's mischaracterizing the toxicity of these compounds, and he's sending it to the wrong people. And it's his opinion. There's just no data that -- there's just -- it's off.
Q. Sorry. Doctor, did you say there's no data? The statement that there's NDMA in valsartan caused by sodium nitrite quenching is an absolutely correct statement. We already talked about that.
A. Yeah.
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. Doctor, that's a correct statement; right?

Page 146

A. Where's the data to back it up? Where's the data prior to this e-mail to back it up?
Q. That's a good question. You would think that they -- it would have been produced to us; right?
MS. ROSE: Object to the form. Adam, please, bringing in your discovery theories into an expert deposition is very inappropriate.
MR. SLATER: I think I can ask any question I want. I'm being told that -- things that I think makes these comments and questions very appropriate, because Dr. Thompson needs to know what position he's taking and what might come.
THE WITNESS: Yeah, the fact that there's no data results that should be present if they knew that, if he ran those experiments and knew it, there would be data. And there's no data. I haven't seen data. That's really the right way to -- I haven't seen the data. If it was available, it would be produced. So without data, that sentence really doesn't carry as much weight as you may think.
BY MR. SLATER:
Q. So it's just an isolated, lucky guess, huh?

Page 147

MS. ROSE: Object to the form.
BY MR. SLATER:
Q. I mean, it was just an isolated, lucky guess that there was NDMA in valsartan in 2017 that was forming due to sodium nitrite quenching? Is that your testimony, Doctor?
MS. ROSE: Object to the form.
THE WITNESS: As I said before, if you look at a table of the cohort of concerns, the first nitrosamine in every table is NDMA. He picked the first one. It's not a lucky guess.
BY MR. SLATER:
Q. Which table are you talking about?
A. Any table I've looked at where they list -- the regulatory -- that toxicology and regulatory affairs paper that you'll look at later. There's a table in there. I'm pretty sure the first one is NDMA. You go to a table, you pick up -- the first one you see, you put it in the e-mail.
Q. Is that a document you have in your file?
A. Yes. You have it now.
Q. Okay. You think that it was a good idea to try to avoid the creation of nitrosamine impurities in sartans?

Page 148

MS. ROSE: Object to the form.
THE WITNESS: Yes. Oh, sorry. Yes.
BY MR. SLATER:
Q. And that's exactly what the patent talked about; right?
A. Yes.
Q. And what they did is they replaced the sodium nitrite with something called hypochlorite so it would not be capable of producing a nitrosamine; correct?
A. Yeah. That's bleach, by the way.
Q. Am I correct?
A. Yes. I think that by doing that, they would have had a worse problem, a worse process.
Q. So going back to your report now, I want to look at the attachments. Exhibit 1 is your CV; right?
A. Hold on. I'm trying to get back there. Let's see. I'm back to my report. What exhibit is that, two?
Q. Exhibit 1 is your CV, your curriculum vitae; correct?
A. Yes.
Q. And that's up to date?
A. No, Exhibit 1 is the deposition notice.

Page 149

Q. No, no, no. I'm talking about your report, which is Exhibit 4, has two exhibits to it.
A. Okay. Yeah. Okay. All right.
Q. The first exhibit to your report is your curriculum vitae; correct?
A. Yes.
Q. And that's up to date?
A. Yes.
Q. You have a list of patents; correct?
MS. ROSE: I want to make clear we produced an additional CV in response to your request for an up-to-date CV prior to the deposition. So this is the CV at the time he submitted his report.
BY MR. SLATER:
Q. Were there any changes made to the CV between the time you served the report and whatever was sent to us more recently?
A. Yeah, I added a number of patents. I added all the compounds I worked on that became commercial, and I added a few more publications as well. But if you're talking about a certain patent I think you're talking about, that didn't change.
Q. All right. We're going to put your up-to-date CV up then.

Page 150

A. Okay, great. You're going to display it on the share screen? This is the up-to-date one? Okay, great.
MS. ROSE: Is this being introduced as an exhibit?
MR. SLATER: I'm trying to get there.
MS. ROSE: Okay.
MR. SLATER: Exhibit 7 now.
MS. ROSE: I just want to make sure the doctor has access to the document on the share file.
BY MR. SLATER:
Q. Exhibit 7 is the up-to-date curriculum vitae we were produced. So Doctor, this is what I want to ask you --
MS. ROSE: It just hasn't come through yet, Adam. Okay, now it's through. I just want to make sure the doctor has the opportunity to look at what you're --
THE WITNESS: Okay. I don't really need to. I know it well enough that I'll just depend on the shared screen for this one.
BY MR. SLATER:
Q. Who knows, maybe I'll ask a couple easy questions.

Page 151

A. Put me to sleep then.
Q. In your curriculum vitae, this up-to-date one we marked as Exhibit 7, there's a list of patents. Are any of them relevant to the issues that you're opining on in this case?
A. No.
Q. In your CV we marked as Exhibit 7, there's a list of research publications. Are any of them relevant to the issues that you're opining on in this case?
A. No.
Q. Let's go to Exhibit 2. We'll come to the amended, don't worry. Looking now at Exhibit 2 to your report, which is Exhibit 4. As of the time you wrote the report, this was the list of materials that you considered?
A. Yes.
Q. And the opinions set forth in your report are based on these materials; correct?
A. Yes.
Q. And then let's put up as Exhibit 8 the up-to-date amended Exhibit 2, please.
In looking at this document, at the end there's a list of other materials. And it looks like five documents were added, one of which

Page 152

was Ministry and Industry Information Technology of the People's Republic of China, Chemical Industry Standard of People's Republic of China, Dimethylamine For Industrial Use published December 4, 2009. Do you see that?
A. Yes.
Q. Did you read that document?
A. That's the one -- that's the one with all the description of the test methods on the CMA. Is that the one -- is that the one that is?
Q. The Chinese standards as described, I think it has some test methods in it for COAs.
A. I believe I did read that one, yes.
Q. And then at the bottom there's four documents with ZHP Bates numbers. Do you see that?
A. Yeah.
Q. When did you get those additional materials, those five new documents that were added to your list of materials?
A. I'd say last week.
Q. Did you know they existed before the last week, or is that when you first found out they existed?
A. Well, I was aware that ZHP had a lot of certificates of analysis for every batch of

Page 153

dimethylamine, so I knew that they must have existed.
Q. How did you know that?
A. Because generally GMP purposes, you can't accept a material for use unless you approve it. And part of the approval process is the certificate of analysis from the supplier.
Q. When you got these materials, we got no supplemental report from you. So I'm assuming they did not change any of your opinions?
A. No, they did not.
Q. Let's put up -- I think it's exhibit -- are we up to eight now, or nine?
MR. GEDDIS: Nine.
MR. SLATER: Exhibit 9 is going to be the English translation of that standard.
THE WITNESS: Okay. Yep.
BY MR. SLATER:
Q. Okay. Is there anything about this standard that's of any significance to you in forming your opinions in this case?
MS. ROSE: Has this been introduced as an exhibit?
MR. SLATER: Let me ask the question differently. This is Exhibit 9.

Page 154

MS. ROSE: Okay. I apologize. Thank you.
BY MR. SLATER:
Q. Doctor, is there anything of any significance to you in this document?
A. I mean, this describes -- scroll down. Is there a certificate of analysis in here?
MS. ROSE: Doctor, you have access to this document on the share site.
THE WITNESS: No, I really have to take a look at the document. What is that, 9?
BY MR. SLATER:
Q. Yes.
A. Okay. So let's see. There is -- oh, yeah, there's a -- a mock certificate of analysis that has the testing methods. So the question is is anything in this document pertinent to my opinions? Is that what --
Q. Was anything that you read in this document significant to you?
A. The only significance it was -- so I could understand the test methods and how they're run for entering the data analysis. That was the significance. I got a deeper understanding of how they test DMF, what they actually do.

Page 155

Q. When you got that understanding, was that significant to you once you learned that information?
A. So the alkalinity test is -- is one that it was unclear. The wording says, you know, an alkalinity of eight percent as a function calculated as dimethylamine. And that wording was a little unclear. So by reading this document, it became clear what that wording actually meant.
Q. What became clear to you?
A. So, yeah, that's total base content. That's not -- that's not necessarily dimethylamine, it's total base content. It could be dimethylamine. It could be carbonate. It could be a few things. So that's -- it's a molecular weight of dimethylamine. That's the number in the formula.
Q. Let's go to page 2 of this document, table one, the technical requirements.
A. Yes.
Q. You see where it says alkalinity in the left-hand column?
A. Alkalinity calculated as dimethylamine.
Q. Are you -- let me ask you this. Have you ever seen this standard before it was given to you

Page 156

in the last week?
A. This -- this certificate of analysis?
Q. This standard. This document. Had you ever seen this before --
A. No.
Q. -- a week ago?
A. No.
Q. Have you ever worked with this document before?
A. No.
Q. Have you -- do you hold yourself out as an expert in the interpretation of this document?
MS. ROSE: Object to the form.
THE WITNESS: Highly skilled, not an expert.
BY MR. SLATER:
Q. The words on the page say that the alkalinity is calculated as dimethylamine; correct?
A. That's what the words say. That's what's unclear about it.
Q. I have to ask the question again. The word on the page says alkalinity calculated as dimethylamine weight by percentage. That's what it says; right?
A. That's what it says.

Page 157

Q. Now let's look at page 6. You see there's a 4.9.5 result calculation. Do you see that heading?
A. Yes.
Q. It says, "The mass fraction of alkalinity calculated as dimethylamine W5 is expressed as a percent and calculated using the formula." And you see the formula there?
A. I do.
Q. And if you go down to the inputs, you see that one of the inputs is an M, a capital M?
A. Yes.
Q. And you see where it says that M equals molar mass of dimethylamine in grams per mole. Do you see that?
A. Yes.
Q. So that's telling you that one of the inputs to the calculation is the molar mass of dimethylamine in grams per mole. That's what this calculation states; correct?
A. That's the mo -- that term M is the molecular weight of dimethylamine. It's not necessarily the dimethylamine content. It's the molecular weight. So the difference is there could be a bunch of different bases in there. It's the

Page 158

total base content, not specifically one. Dimethylamine is a base. It's not specifically that, it's total. Everything.
Q. Let's go with what you just said. One of the bases could be dimethylamine?
A. I said -- I said that -- yeah, one of the bases could possibly be, yes.
Q. So ZHP was aware that one of the potential inputs coming to this manufacturing process with the DMF would be dimethylamine. That's what this is telling us; right?
MS. ROSE: Object to the form.
BY MR. SLATER:
Q. It's a potential input to the process dimethylamine; correct?
A. At such a low level no one would pay attention to it.
Q. New question. One of the things this is telling us is that ZHP was aware that one of the potential inputs to the process when using DMF was dimethylamine; correct?
MS. ROSE: Object to the form.
THE WITNESS: I mean the analytical chemist who filed this document might say that, but -- okay, yes. No, I won't say yes to that. I

Page 159

don't think ZHP was aware. Some low-level working people who file documents saw that and said that's just a number of base. That's how they calculated it. I don't think -- I don't think anybody who saw that, who had access to this document, could interpret that in terms of how it would affect the chemistry in the plant. No way.
BY MR. SLATER:
Q. Didn't ask you that at all. So please try to stay with me on this question.
A. Okay. Sorry for diverting.
MS. ROSE: Please do not characterize what the witness is doing. He's answered your question. You asked a complicated question --
MR. SLATER: You want to comment and tell me that I got a responsive answer when I didn't? I'm not going to be as receptive to what you say, because we both have to be honest with each other, okay? Come on. Please. I've been enormously patient and taking my time through this deposition. But I'll try again. And again, I like Dr. Thompson. We're doing good.
BY MR. SLATER:
Q. I'll try it again. This standard is telling us that ZHP would have been aware that when

Page 160

using DMF, one of the potential inputs to the process, along with the DMF, could be dimethylamine; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, at a number so low you ignore it, but yes.
BY MR. SLATER:
Q. I'll ask it again. Sorry.
A. Okay.
Q. I didn't ask you about what they do with -- the expert on what they do with the information. So I'm not asking you what they do with the information. So I'm not sure why you're throwing that in. You already told me that's not your role here; right?
A. Right.
Q. Okay. So let me just limit it to the question I'm trying to ask, please.
One of the things this standard shows us is that ZHP would have been aware that when it used DMF, that, along with the DMF, dimethylamine could also be introduced to the process; correct?
A. Yes.
MS. ROSE: Object to the form.
THE WITNESS: Oh, sorry. Yes.

Page 161

BY MR. SLATER:
Q. And you've looked at the certificate -- well, let me ask you this. Rephrase.
There's four certificates of analysis listed at the bottom. And I pulled them out. And they're all written in the Chinese language. Do you see that?
A. Yes.
Q. Were those of any significance to you whatsoever?
A. Yes.
Q. You read Chinese?
A. No. I was able to figure out what the -- what the line items were after I read this document.
Q. So you matched it up to that table --
A. Yes.
Q. -- we looked at before?
A. Yes.
Q. And you saw that for two out of the four certificates of analysis you were provided, there actually was some alkalinity measured; correct?
MS. ROSE: Object to the -- object to the form. Are you going to show him the document?
MR. SLATER: I'm asking the question I

Page 162

just asked. I'm trying to save time.
MS. ROSE: It's just not a memory test. So you're asking him to remember numbers in documents.
MR. SLATER: Okay.
BY MR. SLATER:
Q. Do you remember looking at these documents and seeing that two out of the four of them actually calculated having some alkalinity on that line?
A. The effect those numbers had on my opinion was to reinforce it.
Q. Okay. My question is when you saw the four certificates of analysis that you were provided by ZHP, did you note that in two out of those four, there was some alkalinity measured? It wasn't zero. It was more than zero. I'm just asking if you saw that.
A. Yes, I did.
Q. So with those certificates of analysis, ZHP would have been aware that there was the potential that per these suppliers' own certificate of analysis, it was potentially -- it was potentially true that the DMF also contained some amount of dimethylamine. They would have been on

Page 163

notice of that possibility; correct?
MS. ROSE: Object to the form.
THE WITNESS: I think they would have been on notice not to worry about it.
BY MR. SLATER:
Q. Can you answer -- can you answer my question?
They would have been on notice that there was the potential for some dimethylamine to be introduced to the process through this DMF. They would have been on notice of that possibility; correct?
MS. ROSE: Object to the form.
THE WITNESS: Yes.
MR. SLATER: Why don't we take a break for a couple minutes. I want to look at my notes. There's a couple things I'd like to do, but I'd like to organize a little bit. And why don't we come back in about, you know, five or six or seven minutes, and then I'll let you know how much more I have to do, and we'll get going.
THE WITNESS: Okay, great. Thank you.
MS. ROSE: If we could take ten minutes, that would be helpful to me personally.
MR. SLATER: Nina, I am here for you.

Page 164

THE WITNESS: 2:50. You got it.
THE VIDEOGRAPHER: We're off the record at 2:41 p.m.
(Break taken.)
THE VIDEOGRAPHER: We're back on the record at 2:55 p.m.
BY MR. SLATER:
Q. Doctor, I'm going to ask you a few more questions about Exhibit 9, those standards.
A. Yes. Sure.
Q. Let's go to the foreword. It's the third page of the document. It has Roman numeral one. It's the foreword. It's literally the third page in.
A. Third page on that like the -- the foreword. Okay, foreword. That's the page. Yeah. Okay. I'm there.
Q. This points out in the -- so it's talking about some revisions to the prior version of this standard. And it says, "The scope" -- this is the third line, "The scope has been revised from 'applicable to the production of industrial dimethylformamide via the reaction of methylformate with dimethylamine primarily used in pharmaceuticals, pesticides, and organic chemicals

Page 165

to -- applicable to industrial dimethylformamide synthesized by one-step carbon monoxide method and the reaction of methylformate with dimethylamine." Do you see that?
A. Yes.
Q. And that's how you manufacture dimethylformamide, is by a reaction of methylformate with dimethylamine; correct?
A. Yeah, that's what it says.
Q. Did you know that before you got involved in this case, that that's how you create DMF?
A. I might have known that in the distant past. It certainly got reinforced once I got involved with this case.
Q. And let's go now back to the calculation on page 6. You mentioned that the alkalinity could be due to bases including dimethylamine and a few other substances. Can you tell me again what those substances are?
A. So hold on. Let me get to the equation. The possibility -- so one of the possibilities potentially -- I mean, the bases that would be stable in DMF would be a carbonate base. Now I see methoxide for methylformate. There could be methoxide in there. There's a number of different

Page 166

bases that could be in there. Not just -- there's a number of different bases that could be in there.
Q. Well, I want to know the ones that you can identify for me. You said carbonate base or methoxide?
A. Carbonate base -- yeah, so methylformate and methylamine, that will give off methanol, not methoxide. So -- and I don't know if they used carbonate in the process at all, if there are any catalysts that use it. So this -- you know, I don't know exactly if they just mix those two ingredients with no catalyst and heat them up, or what they do, but...
So I'm just -- you know, assuming there's a catalyst, there could be things that come off the catalyst that are bases, like carbonate. You know, that's -- so that's a total base content. Otherwise they would just say this is the amount of dimethylamine in there. Why don't they say that? Why do they say calculated as dimethylamine? There must be other bases in there for them to make a generic formula like that.
Q. You're speculating as to that; correct?
A. I'm speculating.
MS. ROSE: Object to form.

Page 167

THE WITNESS: Yeah, of course I'm speculating. I'm sorry. Yes, I'm -- I didn't put the formula together. I'm speculating.
BY MR. SLATER:
Q. The only base referenced here is dimethylamine; correct?
A. Yes.
MR. SLATER: Dr. Thompson, I'm going to conclude my direct questioning of you. I have all this, but I'm going to try to avoid using it. So hopefully your counsel doesn't ask a lot of questions and I don't have to come back to all that stuff. But subject to what questions are asked, I'm done for now. So thank you.
THE WITNESS: Okay. Great. Thank you.
MS. ROSE: Can we go off the record?
THE VIDEOGRAPHER: We're off the record at 3:00 p.m.
(Break taken.)
THE VIDEOGRAPHER: We're back on the record at 3:35 p.m.
E X A M I N A T I O N
BY MS. ROSE:
Q. Hi, Doctor.
A. Nina, you just blanked out.

Page 168

Q. I apologize. Okay. Apologize. Technical issue. Hi, Doctor. How are you?
A. Hi. Good.
Q. I just have a few questions for you.
A. Okay.
Q. Dr. Thompson, would you agree that your key opinion in this case is that you disagree with the opinions of Drs. Hecht and Najafi that chemists working in the pharmaceutical industry should have known or suspected prior to 2018 that NDMA could form in the valsartan manufacturing process?
A. Yes.
MR. SLATER: Object to the form of the question. It's a leading question. Inappropriate. You can answer.
THE WITNESS: Yes, I disagree with their opinions.
BY MS. ROSE:
Q. And why is that? What is the basis for your disagreement?
A. After I read the supporting documents that they provided with their opinions, it was clear to me that they were using hindsight to make their -- to make their judgment. So that was one thing.

Page 169

The other thing is my -- my -- in all my experience as an organic chemist, I just think that this issue had too many subtleties involved with it for people to recognize the problem. And the last thing is the -- you know, there were two regulatory bodies that reviewed these amendments. There was two amendments and two regulatory bodies. That means there was four different reviews by regulatory bodies with the goal of looking at this thing in terms of safety. That was the goal of evaluating it. Not a single person brought up the issue of NDMA formation. Four -- four chemists from regulatory bodies, zero brought up the issue.
So I really don't think it's -- you can make a statement that chemists would have known this issue. I think from the evidence, it's the opposite. Chemists would not have recognized this issue.
Q. Dr. Thompson, do you recall that you were asked about the many patents and publications on your CV earlier?
A. Yes.
Q. And do you recall that you agreed that they were not relevant to the issues that you're opining on in this case?

Page 170

A. Yeah. So my understanding of that question was that question was directing me do you think your patents and publications are relevant to the synthesis of nitrosamines, the detection of nitrosamines, the synthesis of valsartan or nitrosamines in valsartan. That's what I understood those -- those questions to be about my papers. And so I said no, they're not relevant.

But I think they are relevant in terms of general organic chemistry and using DMF as a solvent, for example, in chemistry. So they are relevant in that respect. As an expert witness in this particular case, my experience in publications are very relevant.

Q. Doctor, do you recall that you testified several times that you're not functioning as the regulatory expert in this case; correct?

A. That's correct.

Q. Do you know if ZHP is presenting a regulatory expert in connection with this litigation?

A. Yes, Ali Afnan.

Q. Okay. And did you review his expert report and deposition testimony?

A. Yes, I did.

Page 171

Q. Okay. And did you rely on his opinions with respect to regulatory issues?

A. With respect to regulatory issues, absolutely, yes.

Q. Okay. Would you agree that you're an expert in the field of organic chemistry?

A. Yes.

Q. And would you agree that you're an expert in the field of process chemistry?

A. Yes.

MR. SLATER: Objection to both questions. Leading.

BY MS. ROSE:

Q. Dr. Thompson, when you used DMF solvent in chemical processes prior to the summer of 2018, were you on notice that dimethylamine was present in DMF?

A. No.

Q. Do you recall talking about the COAs that were associated with the dimethylformamide solvent that was used by ZHP?

A. Yes.

Q. Okay. Do you believe that those certificates of analysis would have put ZHP on notice that using dimethylformamide solvent would introduce dimethylamine into the manufacturing processes in which that DMF solvent was used?

Page 172

A. No. When you read the term calculated as dimethylamine content, as an analytical chemist you know your total base content, total base content. You're not thinking dimethylamine. And also those numbers of those COAs were extremely low. Those are the kind of numbers you look at and you say I don't have to worry about this issue. These are really low numbers.

MS. ROSE: All right. Thank you so much, Doctor. That's all I have.

THE WITNESS: Thanks.

MR. SLATER: We're going to go off the record.

MS. ROSE: Okay.

THE VIDEOGRAPHER: We're off the record at 3:41 p.m.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 3:47 p.m.

E X A M I N A T I O N

BY MR. SLATER:

Q. I just have a few follow-up questions for you.

Page 173

A. Okay.

Q. You talked a little bit about what you based your opinion on, and you said that one of the things you're relying on is the two regulatory bodies reviewed amendments. Those were amendments to what?

A. Those -- those were amendments to the original, I guess the -- so the -- the DMF they changed from ten -- I'm doing my best to recall this. They changed from ten to the triethylene hydrochloride process. That was a DMF. And then there were amendments to that DMF. I believe there were four, maybe five amendments to that. Two of those amendments were -- involved sodium nitrite quenching.

Q. Did you read those amendments?

A. I read the -- I read the amendments that Prinston had. And I'm not that savvy a regulatory person to know if they -- the amendments that Prinston, the drug product manufacturer had, would be the same amendments that ZHP submitted to the FDA. I don't think -- I don't know if they're the same, but I read the ones that Prinston supplied, the drug product manufacturer.

Q. You made clear you're not a regulatory

Page 174

expert; right?
A. Yes.
Q. And you can't tell us right now, based on your own knowledge, what the FDA did with those amendments to evaluate them; right?
A. I assume they read them.
Q. You don't know who would have read them or what they would have done; right?
A. I recall reading from various documents, like Afnan's, that they were read by chemists, organic chemists at those regulatory agencies were some of the people that read those.
Q. You're not testifying that it's within your expertise to know what the FDA did when they reviewed those amendments; right?
A. No. I'm assuming that the FDA read those with an eye towards safety. These --
Q. I didn't mean to interrupt. Had you finished?
A. Yeah. So I'm assuming the FDA read those documents with a particular concern about how that would affect the safety of the -- of the API.
Q. You're joining that assumption, but you don't know that? That's not within your expertise; right?

Page 175

A. That's correct.
Q. You mentioned your CV, that there was something relevant within, I think, either the patents or publications you said with regard to general organic chemistry and the use of DMF. Are your specific -- any of these specific patents or publications specific to the use of DMF?
A. No. Those -- they -- they would include syntheses that used DMF as a solvent, but they don't specifically zero in on studies of DMF itself. Just --
Q. Does it talk about the use of the DMF as a solvent in any considerations of potential impurities and issues like that? Does that actually discuss that at issue which we have in this case?
A. No, it just lists DMF as a solvent, not the -- there was no discussion in any of my work about the impurities of DMF.
Q. And there's no discussion of dimethylamine as a potential impurity of DMF; right?
A. That's right.
Q. And there's no discussion of degradation of DMF to form dimethylamine; correct?

Page 176

A. That's correct.
Q. You mentioned that you had reviewed Dr. Afnan's report; right?
A. Yes.
Q. I have your list -- your amended list of materials reviewed. I don't see any reference to his deposition. You did not see his deposition; correct?
A. I can't -- I can't remember. I definitely read his report.
Q. You told us before that everything was carefully written. I assume if you had read the deposition, it would be listed. And since it's not, that's not something you would have seen; correct?
A. Yeah, that's correct.
MS. ROSE: Object to form.
BY MR. SLATER:
Q. You don't recall any specifics or anything you saw in a deposition of Afnan that's not listed, but there's nothing you independently recall about that; right?
A. No, there's nothing I recall about it specific to him, no.
Q. You testified you relied on Dr. Afnan's

Page 177

opinions on regulatory issues. In essence you would just be able to tell us, based on the reading the report, what his opinions were; correct?
MS. ROSE: Object to form.
THE WITNESS: Yeah. I mean, I viewed him as a gu -- a regulatory guru. I could see what he was saying. I could tell there was a lot of depth behind what he was saying. I relied on it as I would if I was talking to somebody at the FDA. Super qualified guy.
BY MR. SLATER:
Q. What did you specifically rely on him for?
A. So there was in -- in Ramin and Hecht's deposition testimony, there was numerous references to failure to do proper risk evaluation, GMP violations, you know, didn't -- didn't do this GM -- all this guidance, Q3, M7, Q9, Q10. There was a lot of references to regular -- FDA regulatory documents and how ZHP failed to follow any of it. And I thought Afnan systematically debunked every one of those assertions in their testimony.
Q. Those are areas that you've already told us you're not an expert on and you're not going to

Page 178

testify on; correct?
A. That's right. But I relied on him, and he was debunking it, every one.
Q. You mentioned that the certificates of analysis would not have placed ZHP on notice that the DMF would introduce dimethylamine. I wrote it down carefully. That's what you said. Do you recall that?
A. Yes.
Q. And you stand by what you told me when I questioned you that ZHP was certainly on notice of the potential that the DMF it was using could potentially introduce dimethylamine to the process? You still stand behind that testimony; correct?
MS. ROSE: Object to the form.
THE WITNESS: I think low-level people filing documents saw a line about alkalinity, calculated it as dimethylamine. But I don't think that ever put anybody on notice. Those words did not put anybody on notice that dimethylamine could be introduced to the process.
And as I said before, the numbers were so low. They bought the best stuff, the highest quality. The numbers were so low, everybody would say this is not a problem. Let's

Page 179

move on. So I --
BY MR. SLATER:
Q. I didn't --
A. -- I don't agree that it would put them on notice. It would put them on relax.
Q. You didn't do any review of any of ZHP's own internal testing of that DMF; correct?
A. That's right, I did not.
Q. You don't know what the actual numbers were in terms of how much dimethylamine might have actually been in that DMF because you haven't seen any documents of that testing; right?
A. I haven't.
MS. ROSE: Object to form.
THE WITNESS: Yeah, I don't know what testing ZHP did. I know at J-STAR there would have been a lot of numbers on a COA, but we didn't do all -- we didn't repeat all those tests at J-STAR to prove our materials. We would only do a few. So I don't know what they did at ZHP.
BY MR. SLATER:
Q. In terms of your opinions about the significance of the certificates of analysis, you're basing your opinions on what you did in your own work, in your own practice, at your own lab;

Page 180

correct?
MS. ROSE: Object to the form.
THE WITNESS: Yeah, and I'm basing my opinion on the actual number. So the -- the half spec, this is the level it cannot exceed, which is a low number to begin with. The few COAs that I saw were way lower than that. So that's what I based my opinion that this is not a problem on. This would not alert them to a problem is the numbers I actually saw on the supplied material. That's what I --
BY MR. SLATER:
Q. In terms of what -- what that information should have triggered in terms of a risk assessment, you've already told us that's not your expertise. You're not opining on that; right?
A. Yeah, formal risk assessment I'm not -- I'm not an expert on formal risk assessment.
Q. And you didn't evaluate the risk assessment by ZHP? It's not something you talked about in your report; right?
A. All I did was I read through the risk assessment that was in the deviation investigation report.
Q. After the fact.

Page 181

MS. ROSE: Object to the form.
BY MR. SLATER:
Q. The deviation investigation report from after the fact.
A. Yeah, after the fact. I read the deviation investigation after the fact. And the risk assessments all started with this is the problem and worked their way back. They never -- there was nothing in any risk assessments I saw that would allow you to forwardly identify an unknown.
It was always this is the problem we have in our process. Where did this happen in our -- in our company. It was going backwards. So it reinforced my opinion that there was no risk assessment capable of letting them identify this problem.
BY MR. SLATER:
Q. In terms of the standards that were applicable to ZHP in performing its risk assessment from the beginning of the development of the process, you already told me that's not something you opined on. It's not within your expertise; correct?
A. Yes, that's true.

MR. SLATER: I don't have any other questions.
THE WITNESS: Great.
MS. ROSE: Okay. I don't have any questions either. Thank you very much, Doctor, for your time today.
THE WITNESS: Are you going for steak dinner, Adam? Where are you going?
THE VIDEOGRAPHER: One moment. The time is now 3:58 p.m. This concludes today's testimony from Dr. Andrew Thompson. We're now off the record.

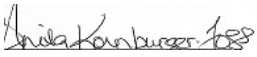
STATE OF WISCONSIN)
) ss.
COUNTY OF MILWAUKEE)

I, ANITA KORNBURGER, Registered Professional Reporter, do hereby certify that the preceding deposition was recorded by me and reduced to writing under my personal direction.

I further certify that said deposition was taken remotely, with all parties appearing by videoconference, on May 9, 2025, commencing at 9:43 a.m. and concluding at 3:58 p.m.

I further certify that I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel, or financially interested directly or indirectly in this action.

In witness whereof, I have hereunto set my hand and affixed my seal of office at Milwaukee, Wisconsin, this 13th day of May, 2025.



ANITA KORNBURGER, RPR

NJ CCR #30X100244300

My certification expires June 30, 2026.

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Rule 30

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